UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES
(v. 12.2018)

Project Title: Building Family Caregiver Skills Using a Simulation-Based Intervention for Care of Patients with Cancer

Principal Investigator: UH Site Principal Investigator: Jennifer A. Dorth, MD
Grant Principal Investigator: Susan R. Mazanec, PhD, RN, AOCN

Patient Consent Form

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?
You are being asked to take part in this research study because you are receiving radiation therapy for head and neck, lung, esophageal, rectal, or anal cancer. Your family caregiver is also being invited to participate. A caregiver is a family member or friend who provides help and support for another person.

Things I should know about a research study
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Introduction/Purpose
The purpose of this study is to learn whether an education and support program can help caregivers feel more confident in technical and communication skills needed to care for a person with cancer. Patients with cancer and their caregivers face many challenges. These include learning about cancer and its treatment, coping with symptoms from illness and treatment side effects, making adjustments to usual activities, and managing the emotional effects of having a serious illness. This study is testing whether different forms of education and support can help caregivers feel better prepared. To find out if education about caregiving and different kinds of support are effective, we want to compare approaches. This information will help us find ways to improve the services that we provide to caregivers during cancer treatment. About 244 patients and their family caregivers at the UH Seidman Cancer Center and MetroHealth Cancer Center will take part in this study.

Key Study Procedures
The research will last about 7 months, from the first week of radiation therapy to 20 weeks after treatment. Your participation will involve providing information about yourself, allowing researchers to collect information from your medical record, and completing surveys four times: at the initial meeting, at the end of treatment, and at 4 and 20 weeks after treatment. More

detailed information about the study procedures can be found under "Detailed Study Procedures."

Key Risks
You may find some of the survey questions upsetting or may feel uncomfortable answering them. More detailed information about the risks of this study can be found under "Detailed Risks"

Benefits
We cannot promise there will be any benefit to you for participating in this study. However, we hope the information we learn will help us improve the care we provide to family caregivers in the future.

Alternatives to Study Participation
Participating in this research is voluntary, which means the choice is up to you. The only alternative to participation in this study is not to participate. This would not have any effect on the medical care that you receive or the services offered to you and your family member at the Cancer Center.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Detailed Study Procedures
Your participation in this study will last about 7 months, from the first week of radiation therapy to 20 weeks after treatment. If you choose to take part, a research assistant will meet with you in the radiation therapy department. At that time you will be asked to complete surveys.

Information about yourself includes your age, race, ethnicity, marital status, employment status, education, annual household income, current living arrangements, and level of activity. We will also collect information from your medical record about your diagnosis, care, treatment, and whether you were admitted to the hospital, visited the urgent care or emergency room, or needed additional intravenous fluids during radiation therapy. We will also ask if you are participating in any mental health and/or support services, such as support groups. We will ask you to complete surveys about how you are feeling physically and emotionally, and your quality of life.

The surveys take about 5 to 10 minutes to complete. The surveys will be sent to you via e-mail. If this is not convenient, or if you would prefer, the research assistant will talk with you in-person at your oncology appointment, by telephone, or you can complete the surveys by yourself

and return them via mail. The research assistant will call you if surveys are not returned within two weeks.

We will also ask you to identify a primary caregiver and to provide his or her contact information. If the caregiver consents to participating in the study and if the caregiver meets the screening criteria, the caregiver will be assigned to one of two groups. One group will include caregivers who will receive an education and support program in addition to usual care by their doctors and nurses. The other group will receive an educational booklet about caregiving in addition to usual care by their doctors and nurses. However, neither you nor the researchers will be able to choose which of these groups the caregiver will be in. Instead, the choice will be made randomly—that is, by chance. A computer will choose which group the caregiver will be in by using a method that is the same as flipping a coin.

The caregiver will also complete surveys about his or her emotions, distress, confidence as a caregiver, and quality of life. In addition, we will ask the caregiver questions about his or her age, race, ethnicity, marital status, employment status, education, annual household income, and current living arrangements. We will ask the caregiver about the hours they spend caregiving, their level of fatigue, and whether they are participating in any mental health and/or support services, such as support groups. The surveys take about 20 to 30 minutes to complete. If your caregiver is assigned to the education and support program, we will offer them an optional interview to share their opinions about the program. They can still join the study if they do not choose to do the interview.

Detailed Risks

Distress Related to Completion of Surveys

There is a possible risk that you may find some of the survey questions upsetting or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question. You may choose to stop the interview at any time. If during the interview, you become upset or indicate feeling very distressed, we will provide a referral to the social worker for further help and support.

Risk of Breach of Confidentiality

There is a chance that someone who is not listed in this form might view your data either by accident or from malicious actions they take to hack the data. To reduce the likelihood of a breach of confidentiality, all researchers have been thoroughly trained to maintain your privacy. Your name will not be attached to any of the information we collect about you. Instead, we will assign you a study ID number for use on the survey forms. Only the study team will have access to the records that link your name to your study ID number. Information will not be shared with your Cancer Center doctors and nurses without your permission. Research records will be kept in

locked files with limited access and/or password-protected computer files. We will not list your identity in any reports or publications about this research.

Financial Information

There is no cost to you or your insurance for being in this study. For your participation in this research study, you will receive a $20 gift card after completing surveys at 4 and 20 weeks after radiation treatment, for a total of $40. The gift cards will be given to you in person, emailed or mailed to you.

Clinical Trial Information

U.S. NATIONAL INSTITUTES OF HEALTH (NIH) CLINICAL TRIAL DATABASE: 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 to find out information about the trial and basic results.

Termination of Participation

Your participation in this study may be discontinued by the investigator if you stop radiation treatment and/or enroll in hospice care.

Confidentiality

Your name will not be attached to any of the information we collect about you. Instead, we will assign you a study ID number for use on the survey forms. Only the study team will have access to the records that link your name to your study ID number. Research records will be kept in locked files with limited access and/or password-protected computer files. We will not list your identity in any reports or publications about this research.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Privacy of Protected Health Information (HIPAA)

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared

within and outside of University Hospitals. This Authorization form is specifically for a research study entitled "Building Family Caregiver Skills Using a Simulation-Based Intervention for Care of Patients with Cancer" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Jennifer Dorth, MD; Susan Mazanec, PhD, RN; and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you: name, address, phone number, age, gender, race, ethnicity, marital status, employment status, education, income, and living arrangement; diagnosis, care, treatment, and whether you were admitted to the hospital, visited the urgent care or emergency room, or needed additional intravenous fluids during radiation therapy; your participation in any mental health and/or support services; how you are feeling physically and emotionally; and your quality of life. This PHI will be used to learn whether an education and support program can help promote confidence for caregiving in family caregiver. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: University Hospitals Institutional Review Board; Case Comprehensive Cancer Center Protocol Review and Monitoring Committee; The Study's Data Safety and Monitoring Board; the study's sponsor – The National Cancer Institute; other staff from the Principal Investigator's medical practice group; University Hospitals, including the Center for Clinical Research and the Law Department; and Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in

writing by sending a letter to: [redacted]

If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, [redacted] Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Summary of Your Rights as a Participant in a Research Study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of Your Study Records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. In addition, for treatment studies, the study sponsor may also review your records. If your records are reviewed your identity could become known.

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Contact Information

_____has described to you what is going to be done, the risks, hazards, and benefits involved. The Grant Principal Investigator, Dr. Mazanec can also be contacted at 216-368-2016. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at [redacted] or write to: The Associate Chief Scientific Officer, The Center for Clinical Research, [redacted]

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

x	
Signature of Participant	Date/Time
x	
Printed Name of Participant	
x	
Signature of person obtaining informed consent	Date/Time
x	
Printed name of person obtaining informed consent	