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PATIENT CONSENT FORM

An inpatient advance care planning intervention for older patients with hematologic malignancies

Principal Investigator:
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This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully.

The study staff will explain this study to you. Please ask questions about anything that is not clear before you agree to participate or at any time. You may take this consent form home to think about and discuss with family or friends.

Key Information

- Being in this research study is voluntary – it is your choice.
- You are being asked to take part in this study because you are aged 60 or older and have a blood cancer.
- The purpose of this study is to assess whether an inpatient advance care planning intervention improve outcomes. As a participant of this study, you would take part in an advance care planning visit with an advanced practice provider (APP) [includes both physician assistants (PA) and nurse practitioners (NP)] or a hematology oncology fellow (i.e., physician who is training to be a hematologist and oncologist).
- Your active participation will last approximately 4 weeks.
- Procedures will include participating in interviews, completing physical and cognitive assessments, and completing follow-up questionnaires to assess your experience in the study.
- The most common risk is loss of confidentiality.

Introduction

You are being asked to take part in this study because you are aged 60 or older and have a blood cancer. This form describes the known possible risks and benefits of the study. You are completely free to choose whether or not to participate in this study.

Advance care planning involves learning about the types of decisions that might need to be made, considering those decisions ahead of time, and then letting others know (both your family and your healthcare providers) about your preferences. These conversations often do not happen until late in the disease process. Incorporation of an advance care planning intervention while you are in the hospital may improve your experience.

This study is being conducted by Dr. Kah Poh (Melissa) Loh from the University of Rochester's Division of Hematology/Oncology, Department of Medicine.

Purpose of Study

The focus of the study is to test an advance care planning intervention in the hospital. This conversation with the APP or hematology oncology fellow will happen while you are in the hospital. We would like to find out whether the intervention improves outcomes in older patients with blood cancer.

Description of Study Procedures

If you decide to take part in this study, you will be asked to do the following:

- Complete questionnaires asking questions about your demographics, physical function, mood, social support, advance care planning engagement, and understanding about your cancer and basic health information. These forms will take you approximately 20-25 minutes to complete.
- We will perform a measure of your cognition. We will ask you some questions to evaluate your orientation, memory, concentration, and language.
- Participate in an audio-recorded advance care planning visit with an APP or hematology oncology fellow (and caregivers if applicable) while you are in the hospital.
- Participate in an audio-recorded interview after the visit during which we will explore your preferences and feedback regarding the intervention.
- Complete questionnaires regarding your thoughts on the intervention.
- You can choose a caregiver to participate with you in the study, but you may still participate if a caregiver does not participate with you.
- If your caregiver has agreed to participate in the study, we will ask your caregiver to participate in an audio-recorded interview during which we will gather feedback.

Information about your study participation and study results may be included in your electronic health record. If you have concerns about this or to obtain more detail, you should discuss this with the study team.

Number of Subjects

Approximately 50 patients and 100 caregivers will take part in the study. We will consent up to 75 patients and up to 150 caregivers (Up to 2 caregivers for each patient). These patients will be recruited from Wilmot Cancer Institute.

Duration of the Study

Your active participation will last approximately 4 weeks. For us to complete the study and understand the results, we will need to access information from your medical record for up to 5 years after you complete the study.

Sponsor Support

The study is funded by the University of Rochester Quality Institute.

Costs

There will be no cost to you to participate in this study.

Payments

You will receive a $10 gift card for your participation in this study.

For this study, we use a subject payment system called Advarra Participant Payments. The system allows three ways to provide payment. You can choose: a reloadable debit card, direct deposit, or mailed paper checks. The study team will help you create a "subject profile" in the system. In order to provide payment, you will need to enter your name and date of birth into your subject profile. Depending on which payment method you choose, you may also need to enter your email address and banking information. If you already have an Advarra account (because you are in another study that uses this system), your existing profile will be used to provide payment. See the '**Information Sheet for Advarra Participant Payments**" provided with this consent for additional information.

Payment received for participation in research is considered taxable income. If you receive payment for your taking part in studies at the University of Rochester of $600.00 or more in any one calendar year, the University is required to report this information to the Internal Revenue Service (IRS) in a 1099 (Miscellaneous Income) form. You will be sent a copy of this form and a copy will be sent to the IRS. You may be asked to complete a W-9 form, which includes your Social Security Number. If you are asked to complete a W-9 form and we find that you are not a US citizen or permanent resident, we may need to withhold 30% of your payment for taxes consistent with tax requirements.

Benefits of Participation

You might not benefit from being in this research study.

Risks of Participation

The study has minimal risk. While we will make every effort to keep information we learn about you private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law.

The risk associated with this study includes loss of privacy and because we will collect medical and personal data from you and your medical record. Protected health data and personal data will be kept as confidential as it can be, but complete confidentiality cannot be guaranteed.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website at any time.

The study team may be notified if you receive other health care services at URMC or its Affiliates (e.g., visit to the emergency room). In addition, the following individuals may know you participated in research and may see results of testing conducted for this study:

- Staff at the University of Rochester Medical Center and its Affiliates (e.g., Strong Memorial Hospital, Highland Hospital, URMC primary care, specialist physician offices) who have a reason to access your electronic health record.
- Health care providers who are involved in your care at a facility that is not part of the University of Rochester Medical Center and its Affiliates and who have reason to access your electronic health record.
- Individuals who request a copy of information from your health record for activities such as treatment or payment (e.g., medical insurance companies, worker's compensation).

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

Because this study involves collecting personal, identifiable information about you, there is a potential for invasion of privacy or breach in confidentiality. The University of Rochester will make every effort to keep the information collected from you private. To minimize this risk, we will assign you a study number instead of labeling the information we collect from you with your name or medical record number. All of the information we collect will be stored securely and only study team members will have access to it.

Sometimes researchers need to share information that may identify you with people that work for the University. If this does happen, we will take precautions to protect the information you have provided.

Results of the research may be presented publicly at meetings or in publications, but your name or identifying information will not be used.

Audio-recorded interviews will be transcribed by a professional transcription service called ExecuScribe. Both the audio-recorded interviews and interview transcripts will be kept for 7 years after the study and all reports and publications are complete.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Past and present medical records related to the study

Who may use and give out information about me?

- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester
- Advarra Participant Payments (for the purpose of registering you for payment)
- ExecuScribe (for the purpose of transcription)

Why will this information be used and/or given to others?

- To do the research
- To study the results
- To see if the research was done right

What if I decide not to give permission to use and give out my health information?

- Then you will not be able to be in this research study.

May I review or copy my information?

- Yes, but only after the research is over.

How long will this permission be valid?

- This permission will last indefinitely.

May I cancel my permission to use and disclose information?

- You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

How long will my health information be kept?

- We will keep your information for 7 years after study completion. Your information will be destroyed after.

May I withdraw from the study?

- Yes, you may withdraw from the study. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

- No. There is a risk that your information will be given to others without your permission. Once your information is disclosed to the named entities or organizations listed above, it is possible that your medical information will be re-disclosed and will no longer be protected by U.S. federal privacy regulations.

Use of E-mail for Communication in Research

You may receive communication about this study via email.

Email communications may be used to complete baseline and post-intervention activities, schedule study visits, and schedule your end-of-study interview. You may be sent reminder emails to complete tasks. Documents may be sent to you via email for your records.

Email communications may be sent or received in an unencrypted (unprotected) manner. Therefore, there is a risk that the content of the communication, including your personal information, could be shared beyond you and the research team. Your consent below indicates that you understand this risk. The University of Rochester is not responsible for any interception of messages sent through email. Email communications between you and the research team may be filed in your research record.

Sending your information by email has a number of risks you should consider:

- E-mail can be circulated, forwarded, stored electronically and on paper, and broadcast to unintended recipients.
- E-mail senders can easily misaddress an e-mail.
- Backup copies of e-mail may exist even after the sender or the recipient has deleted his or her copy.
- Employers and online services have a right to inspect e-mail transmitted through their systems.
- E-mail can be intercepted, altered, forwarded, or used without authorization or detection.
- E-mail can be used to introduce viruses into computer systems.

These are the conditions for e-mail communication between you and the researcher:

- E-mail is not appropriate for urgent or emergency situations. The researcher cannot guarantee that any particular e-mail will be read and responded to.
- E-mail must be concise. You should schedule an appointment if the issue is too complex or sensitive to discuss via e-mail.
- E-mail communications between you and the researcher will be filed in your research record.
- Your messages may also be delegated to any member of the study team for response.
- The researcher will not forward subject-identifiable e-mails outside of URMC and Affiliates without your prior written consent, except as authorized or required by law.
- You should not use e-mail for communication regarding sensitive medical information.
- It is your responsibility to follow up and/or schedule an appointment if warranted.
- Avoid use of your employer's computer.
- Put your name in the body of the e-mail.
- Put the topic (e.g., study question) in the subject line.
- Inform the researcher of changes in your e-mail address.
- Take precautions to preserve the confidentiality of e-mail.
- Contact the researcher's office via conventional communication methods (phone, fax, etc.) if you do not receive a reply within a reasonable period of time.

**********End of Section**********

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. If you do withdraw from this study, the information you have already provided will be kept confidential.

Contact Persons

For more information concerning this research or if you feel that your participation has resulted in any emotional or physical discomfort please contact: Dr. Kah Poh (Melissa) Loh at (585) 275-5863. For questions about this study please contact the Study Coordinator at 585-275-4391.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

**********End of Section**********

SIGNATURE/DATES

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

_____

Subject Name (Printed by Subject)

_____ _____

Signature of Subject Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____

Name and Title (Print)

_____ _____

Signature of Person Obtaining Consent Date