Informed Consent/Authorization for Participation in Research

Title of Research Study: Communicating Health Options to Inform Care and Empower Strategic care planning (CHOICES): A Multi-Layer Randomized Case Vignette Study

Study Number: 2024-0531

Principal Investigator: David Hui, MD

Participant's Name | Medical Record Number

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 invited to take part in a research study because you have been diagnosed with advanced cancer and have received at least 2 lines of systemic therapy.

What should I 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.

Why is this research being done?

The goal of this research study is to learn more about how the delivery of medical information affects therapy choices for patients with advanced forms of cancer.

How long will the research last and what will I need to do?

You will be asked to complete several questionnaires on this study with about 150 questions about your quality of life, anxiety, health, andcase scenarios that are not real or based on your actual health situation. It should take about an hour to complete all the questionnaires, though it may take longer for some participants. Your participation in the study will be over after you finish all questionnaires.

More detailed information about the study procedures can be found under ***"What happens if I agree to be in this research?"***

Is there any way being in this study could be bad for me?

There are no likely physical risks, but the main potential harms include loss of time, possible frustration, mental stress or anxiety, and loss of privacy/confidentiality. The case scenarios that are not real or based on your actual health situation may cause distress.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. It cannot be promised that there will be any benefits to others from your taking part in this research. Future patients may benefit from what is learned.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate, not participate, or discontinue participation at any time without penalty or loss of your regular benefits.

Your alternative to participating in this research study is to not participate.

Detailed Information

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

Who can I talk to if I have questions or concerns?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 713-792-6085.

This research has been reviewed and approved by an Institutional Review Board ("IRB" - an ethics committee that reviews research studies). You may talk to them at 713-792-6477 or IRB_Help@mdanderson.org if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be in this study?

It is expected that about 400 people at MD Anderson will be enrolled in this research study.

What happens if I agree to be in this research?

If you agree to take part in this study, you will complete about 16 questionnaires that will have questions about your quality of life, anxiety, health, andcase scenarios that are not real or based on your actual health situation.. It should take a bit more than an hour to complete all the questionnaires. If you find that any of these questions are difficult to read, understand, or otherwise complete; or if they cause distress, you may ask the study team for clarification, skip the question, or even stop the study at any time.

Additionally, information will be collected from your medical record about your health and treatment, as well as your demographic information (age, race, sex, and so on). We may also ask you for additional demographic information not found in your medical record.

What happens if I say yes, but I change my mind later?

You can leave the research at any time; it will not be held against you. If you withdraw from this study, you can still choose to be treated at MD Anderson.

Is there any way being in this study could be bad for me? (Detailed Risks)

Questionnaires may contain questions that are sensitive in nature, including questions about your quality of life, anxiety, health, andcase scenarios that are not real or based on your actual health situation, which may cause distress. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact your doctor or the study chair. If you are feeling distressed and the study staff or doctor thinks it is needed, you will be referred to another doctor or therapist for additional help.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

In addition to these risks, this research may hurt you in ways that are unknown.

For pregnant participants, there are no known risks to the fetus beyond the general risks to the participants as stated above.

You will be told about any new information that may affect your health, welfare, or choice to stay in the research.

Will it cost anything to be in this study? Will I be paid to be in this study?

This study will be performed at no cost to you. If you complete all the questionnaires, you will receive a $10 gift card.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who need to review this information. Complete secrecy cannot be promised. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Any personal information that could identify you will be removed or changed before data are shared with other researchers or results are made public.

Federal law provides additional protections of your medical records and related health information. These are described below.

Will my data be used for future research?

Your personal information is being collected as part of this study. These data may be used by

researchers at MD Anderson or shared with other researchers and/or institutions for use in future research.

In some cases, all of your identifying information may not be removed before your data is used for future research. If future research is performed at MD Anderson, the researchers must get approval from the MD Anderson IRB before your data can be used. At that time, the IRB will decide whether or not further permission from you is required. If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data.

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or shared with another researcher for future research studies without your additional informed consent.

What else do I need to know?

MD Anderson may benefit from your participation and/or what is learned in this study.

Your information (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - The Office for Human Research Protections (OHRP)
   - The IRB and officials of MD Anderson
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will do its best to protect the privacy of your records, but it is possible that once information is shared with people listed on this form, it may be released to others. If this happens, your information may no longer be protected by federal law.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ Date/Time: _____

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ Date/Time: _____