THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Technology-Enhanced Palliative Care for Cancer Patients in Early Phase Clinical Trials
2019-1052

Subtitle: Patient Consent Form

Study Chair: Ishwaria M. Subbiah

_____ _____
Participant's Name Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

STUDY SUMMARY

The goal of this research study is to learn if the Technology-Enhanced Palliative Care [TEC] symptom-monitoring program, when combined with in-person clinic visits and standard remote care visits (by phone or video call), helps increase quality of life and care for patients with advanced cancer enrolling or participating in Phase 1 and Phase 2 clinical trials.

This is an investigational study.

Future patients may benefit from what is learned. There are no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including potential expenses and time commitment.

You can read a list of potential risks below in the Possible Risks section of this consent.

You will take part in this study for up to 12 weeks, as long as the study doctor thinks it is in your best interest.

There will be no cost to you for taking part in this study. However, there may be a cost to you for telephone and/or internet charges.

You may choose not to take part in this study.

1. STUDY DETAILS

Up to 298 patients will be enrolled in this study. All will take part at MD Anderson.

Baseline Visit

If you agree to take part in this study, your demographic information (such as date of birth, gender, race/ethnicity, details about your cancer, and so on) will be collected from your medical record. You will also complete 4 questionnaires. These questionnaires contain questions about your level of delirium (loss of contact with reality), any symptoms you may be having, your quality of life and overall well-being, and your satisfaction with outpatient supportive care. These questionnaires will take about 15 minutes total to complete.

Study Groups and Visits

You will be randomly assigned (as in a coin flip) to 1 of 2 groups. This is done because no one knows if one study group is better, the same, or worse than the other group. You will have an equal chance of being in each group.

If you are in **Group 1**, you will receive standard symptom management by the supportive care team. This will be done with an in-person clinic visit or remotely by phone or a video-conferencing platform such as Zoom, Skype, or FaceTime at least 1 time every 4 weeks according to your standard of care.

If you are in **Group 2**, your symptoms will be monitored at in-person clinic visits or remotely by phone or video call at least 1 time every 4 weeks according to your standard of care. The following procedures will also be performed **1 time every week for the first 2 weeks**, **and 1 time every other week during your trial for 12 weeks:**

- You will complete up to 4 questionnaires about any symptoms you are having, your quality of life and overall well-being, and your satisfaction with outpatient supportive care. These questionnaires will be completed online through an electronic patient portal and should take about 15 minutes to complete. If you do not complete these questionnaires, you will be sent up to 4 reminder emails to complete them.
- A primary care (PC) clinic nurse will contact you by phone or video call to ask you about your questionnaire responses, your health since your last clinic visit or phone/video call, and any new symptoms you are having. These phone/video calls should take up to 10 minutes.

However, for all study groups, the supportive care team may follow up with you outside of these time points, if needed for your care.

During Week 8 (both study groups), you and your caregiver may be asked to take part in an interview with the supportive care nurse. The interview will be about your experiences during the Phase 1 or Phase 2 clinical trial. It can be completed in person or remotely by phone/video call and should take about 45 minutes. You may be asked to complete the interview separately from your caregiver. The interview will be audio-recorded and transcribed (written down). Transcripts and audio-recorded tapes will be kept without a set time limit for use in future research.

2. POSSIBLE RISKS

You should discuss the risks of questionnaires with the study doctor. The known risks are listed in the form, but they may vary from person to person.

Questionnaires and interviews may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaires and interviews, you are encouraged to contact your doctor or the study doctor.

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. 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.

This study may involve unpredictable risks to the participants.

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson or American Cancer Society (ACS) for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

As compensation for your time and effort, you will be given a $100 gift card for completing the interview.

Additional Information

4. You may ask the study chair (Dr. Ishwaria Subbiah, at 713-792-6085) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you withdraw from this study, you can still choose to be treated at MD Anderson.

6. This study or your participation in it may be changed or stopped at any time by the study chair, American Cancer Society (ACS), or the IRB of MD Anderson.

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

8. This study is sponsored and/or supported by: American Cancer Society (ACS).

9. In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s)/supporter. If you have any questions about this, you may call the IRB at 713-792-6477.

Future Research

Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and American Cancer Society (ACS) and/or shared with other researchers and/or institutions for use in future research.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data.

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

A. During the course of this study, MD Anderson will be collecting and using 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:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
   - The IRB and officials of MD Anderson
   - American Cancer Society (ACS), and the Andrew Sabin Family Foundation, who are sponsors or supporters of this study, and/or any future sponsors/supporters of the study
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

   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 if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

   Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

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 of MD Anderson 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.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

LEGALLY AUTHORIZED REPRESENTATIVE (LAR)
The following signature line should only be filled out when the participant does not have the capacity to legally consent to take part in the study and/or sign this document on his or her own behalf.

_____ _____
SIGNATURE OF LAR DATE

_____
PRINTED NAME and RELATIONSHIP TO PARTICIPANT

WITNESS TO CONSENT
I was present during the explanation of the research to be performed under Protocol **2019-1052**.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE
A witness signature is only required for vulnerable adult participants. If witnessing the assent of a pediatric participant, leave this line blank and sign on the witness to assent page instead.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

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.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into_____and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

_____ _____ _____
NAME OF TRANSLATOR SIGNATURE OF TRANSLATOR DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line below.)

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION DATE
(OTHER THAN TRANSLATOR, PARENT/GUARDIAN,
OR STUDY CHAIR)

_____
PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION