THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Patient Perceptions of the Relational Empathy of Healthcare Practitioners from the Department of Emergency Medicine during COVID-19: A Randomized, Controlled Trial Comparing In-Person Interaction with Personal Protective Equipment (PPE) versus Video Interaction without PPE

2020-1298

Study Chair: Kumar Alagappan, MD

_____ _____
Participant's Name Medical Record Number or Study ID

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 whether patients who visit the Acute Cancer Care Center at MD Anderson believe they get better (more empathetic) care from doctors who visit them in person wearing personal protective equipment (PPE) or from doctors who visit them by video call and do not need to wear PPE.

This is an investigational study.

Future patients may benefit from what is learned in this study. 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 may choose not to take part in this study because you are not interested in completing the questionnaire.

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

Your participation on this study will be complete after you complete the questionnaire.

There will be no cost to you for taking part in this study.

You may choose not to take part in this study.

1. STUDY DETAILS

Up to 106 participants will be enrolled in this study. All will take part at MD Anderson.

You have had your initial conversation with the doctor in the Acute Cancer Care Center. If you agree to take part in this study, you will be randomly assigned (as in the flip of a coin) to 1 of 2 study groups for the rest of your visit today, including any follow-up or discussion of test results. This randomization is done because no one knows if one group is better, the same, or worse than the other.

- If you are assigned to the **Video Interaction/Without PPE Group**, you will meet with the doctor by video call for the rest of your visit. The doctor will not wear any PPE during the video call(s). A tablet computer will be positioned close to you for the video call(s). Your doctor will call you from a nearby room.
- If you are assigned to the **In-Person/PPE Group**, you will continue to meet with the doctor in person for the rest of your visit. The doctor will wear the appropriate PPE during the in-person visit(s).

Your care in the Acute Cancer Care Center will not be affected by which group you are assigned to, because your workup plan (what your doctor needs to know to make a diagnosis) was decided on and discussed with you before joining this study. Being assigned to the video group will not prevent you from receiving in-person reassessment or emergency care, if you need it.

After all conversations with your doctor have been completed and you are ready to leave the Acute Cancer Care Center, you will complete 2 brief questionnaires about your interactions with your doctor. These questionnaires will be completed on a tablet computer or on paper in your Acute Cancer Care Center room and should take less than 10 minutes to complete. If the questionnaires are turned in but appear to be incomplete, the study staff may approach you to ask you to complete the missing items.

Your participation in this study will be complete after you finish the questionnaires. Study staff will collect certain relevant information about you (birth date, sex, ethnicity, race, education level, marital status) from you or from your medical record.

2. POSSIBLE RISKS

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

make you feel upset or uncomfortable. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaires, you are encouraged to contact your doctor or the study chair.

Information about your care is being collected by the study staff for research purposes only, and not for any diagnostic reasons.

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. There will be no personal identifying information connected to your questionnaire/interview answers.

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 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.

Unless otherwise stated in this consent form, all of the costs linked with this study, which are not covered by other payers (health maintenance organization [HMO], health insurance company, etc.), will be your responsibility.

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

You will receive no compensation for taking part in this study.

Additional Information

4. You may ask the study chair (Dr. Kumar Alagappan, at 713-745-9911) 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 without your consent at any time by the study chair or the IRB of MD Anderson.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

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

Future Research

Data
Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson for 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.

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

A. During the course of this study, MD Anderson may be collecting and using your PHI. For legal, ethical, research, and safety-related reasons, 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

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, health authorities 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.

E. 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 Web site at any time.

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 **2020-1298.**

_____ _____
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