THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Positive Activities for Asian American Cancer Patients and Caregivers 2021-0998

Subtitle: Patients

Study Chair: Qian Lu

_____ _____
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.

This research has been reviewed and approved by an Institutional Review Board (IRB - a committee that reviews research studies).

STUDY SUMMARY

The goal of this research study is to learn if performing simple activities can help to improve the quality of life of Asian-American cancer patients.

This is an investigational study.

Taking part in this study may result in improved quality of life for you. Future patients may benefit from what is learned. There may be 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 time commitment.

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

You will be in this study for about 6 weeks. If you are selected for the interview part of this study, your participation in this study will be over after the interview. If you are not selected for the interview part, your participation will be over at the end of the intervention (described below).

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

You may choose not to take part in this study.

Your caregiver may also be asked to take part in this study. If they choose not to take part in this study, you can still participate without them.

1. STUDY DETAILS

If you agree to take part in this study, the study team will collect information about you from your medical record. This will include demographic information (date of birth, race, sex, language preference, and so on), medical information (cancer diagnosis and stage and the name of your main cancer doctor), and your contact information (email address).

You will then be randomly assigned (like the roll of dice) to 1 of 3 study groups. Neither you nor the study team will be able to choose your study group assignment. You have an equal (about 33%) chance of being assigned to each group.

Depending on your group assignment, you may be asked to perform certain activities 1 time a week for 4 weeks to see if they can improve your quality of life. You will also be asked to record your activities using an online system called REDCap. The study team will provide specific instructions about the activities you may be asked to perform.

The study team may email you every other day during your participation in this study to give more information about the assigned activities and remind you to record your activities in the system. The study team may also text you reminders if you are not completing the study activities.

Up to 60 participants (30 patients and up to 30 caregivers) will be enrolled in this study. All will take part at MD Anderson.

Questionnaires
Before, halfway through, and at the end of your assigned intervention, you will be asked to complete online questionnaires about your personal information (such as your age, race, and income) and your quality of life. The questionnaires should take about 20 minutes to complete each time.

If your caregiver is also participating in this study, you should complete these questionnaires in a private setting away from your caregiver so that your answers do not influence one another. The researchers will keep your questionnaire responses confidential and will not share them with your caregiver.

Interviews
After you complete your assigned intervention, you may be asked to take part in an

interview about your participation in this study. The interview may be performed at MD Anderson or online using Zoom (a video conferencing application). It should take about 30 minutes to complete the interview.

During the interview, the study doctor will ask you questions about your experience with the study activities. Your interview responses will be kept confidential.

The interview will be recorded and transcribed (written down).

2. POSSIBLE RISKS

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 questionnaire, you are encouraged to contact your doctor or the study chair.

You may experience some distress when participating in the study activities or answering questions about your emotional state, but this distress should be no greater than what you experience in everyday life.

If you are found to be under severe distress, emotionally or physically, during the course of the study, the study team will report your symptoms to your doctor/medical provider. This will also be communicated to you so that you may also report your symptoms to your doctor/medical provider.

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 up to $70 for your time and efforts in this study ($25 after the completion of the midpoint questionnaires, $25 after the end of your study participation, and $20 if you are selected for an informational interview). If you

withdraw before the midpoint questionnaires, you will not be paid for your participation in this study. If you withdraw after the midpoint questionnaires but before the end of the study, you will only be paid $25.

Additional Information

4. You may ask the study chair (Dr. Qian Lu, at 713-745-8324) 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.

9. This study is sponsored and/or supported by: the National Institutes of Health (NIH) and National Cancer Institute (NCI).

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/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.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

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
   - National Institutes of Health (NIH) and National Cancer Institute (NCI), who is a sponsor or supporter 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, 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

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