THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

Liver Cancer Prevention Study in the Houston Community - Aim 1
2019-0978

Study Chair (the person in charge of this study): Dr. Jessica P. Hwang

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

This is an informed consent and permission form for a research study. The HOPE Clinic and MD Anderson are teaming up to learn how to prevent liver cancer. This research has been reviewed and approved by an Institutional Review Board (IRB - a committee that reviews research studies).

If you have any questions about anything in this form, please ask us. If you have questions later, please contact the researcher in charge of the study.

This form may be hard to understand. If you want, the research staff will read it with you.

If you have any questions, you may ask them at any time – before, during, or after you are in the study.

STUDY SUMMARY

The goal of this research study is to learn more about how to prevent or find liver cancer in patients who are currently receiving care at the HOPE Clinic.

This is an investigational study.

Taking part in this study may help you know whether you have hepatitis B and C, liver fibrosis, and liver cirrhosis. Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. You do not have to be in this study. Please ask as many questions as you would like before you decide if you want to be in this study.

Any research study can have risks and benefits. To see a list of possible risks when you are in the study, please read the Possible Risks section of this consent.

You will be in the study for up to 3 months. It will include 1 or 2 visits that will happen when you are seen at HOPE Clinic.

The hepatitis tests and Fibroscan (imaging of the liver that is done in the clinic) done as part of this study will be done at no cost to you. You and/or your insurance company will be responsible for the costs of your medical care at HOPE Clinic.

You may choose not to take part in this study. It is okay to say no. If you join the study but later change your mind, you can leave the study at any time. The care that you receive at HOPE Clinic will not change if you decide you do not want to take part in this study.

1. STUDY DETAILS

If you agree to take part in this study, the following will be done at the HOPE Clinic:

- You will complete a questionnaire about your risk of having hepatitis B virus or hepatitis C virus and your alcohol use. You will answer questions about your life and behaviors that can affect your chance of getting the hepatitis B or hepatitis C virus. These include questions about your health, blood disorders, sexually transmitted diseases, and alcohol and drug use. It should take about 10-15 minutes to complete. If you need help reading or completing the questionnaire, the study staff can help you.
- You will have a test called a Fibroscan of your liver (which uses a probe like an ultrasound). This test is done to check if your liver has any fat in it and to check for signs of stiffening or hardening of the liver.
- Blood (about 1½ tablespoons) will be drawn for routine tests and to test for hepatitis B and C. This will be done during an already-scheduled blood draw to avoid an additional needle stick. If the test is positive for hepatitis, you will be asked to come back for a second visit where an additional blood sample (about 1 tablespoon) will be drawn to confirm the results. If you are found to be hepatitis positive, the HOPE Clinic will provide care for you and will explain what this means for you.
- Information about the care and treatment you receive at the HOPE Clinic will also be collected. The study staff will also collect the results of your routine and hepatitis blood tests and the Fibroscan.

If the tests show that you have hepatitis B or C, high blood sugar or cholesterol (which may be related to diabetes or heart problems), high alcohol use, or signs of liver hardening/stiffening (called fibrosis and cirrhosis), the HOPE Clinic staff will contact you. You may be asked to come back to the clinic to have more tests done to check on your health. This will be part of your standard care. The HOPE Clinic staff will know your test results within 1-2 weeks of when your blood is drawn. The

HOPE Clinic staff will let you know your test results by telephone call or video telephone call, if available.

2. POSSIBLE RISKS

Questionnaires may contain questions that may make you sad or upset. You do not have to answer any questions you do not want to answer. Please ask the research team if you have any questions.

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

There are no known risks for the **Fibroscan** of your liver.

OPTIONAL PROCEDURES FOR THE STUDY

Optional Procedure #1: If you agree, extra blood (about 1½ tablespoons) will be drawn and stored in a research bank at MD Anderson for use in future research related to cancer and/or other diseases. Blood for future research will be drawn at the same time as blood for routine tests to avoid an additional needle stick.

Before your samples can be used for research, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson. The IRB is a committee of doctors, researchers, and community members. The IRB is responsible for protecting study participants and making sure all research is safe and ethical.

Your samples will be given a code number. Only individuals with IRB permission and designated bank staff will have access to the code numbers and be able to link the samples to you. This is to allow medical data related to the samples to be updated as needed. Additionally, if needed for certain types of research in the future and if the IRB approves, the bank staff and approved research staff will be able to link your samples back to you.

You do not have to agree to the optional procedure in order to take part in this study. There are no benefits to you for taking part in the optional procedure. Future patients may benefit from what is learned. You may stop taking part at any time. There will be no cost to you for taking part in the optional procedure.

Optional Procedure Risks

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count),

which may create a need for blood transfusions.

MD Anderson and others can learn about cancer and other diseases from your **banked samples**. In the future, people who may do research with these samples may need to know more information about your health. This information may be collected from your medical record. MD Anderson will make reasonable efforts to preserve your privacy, but cannot guarantee complete privacy.

If you withdraw your consent to the storage of samples in the research bank, then any of your samples that remain in the bank will no longer be used for research and will be removed from the bank and destroyed.

However, if any of your de-identified samples were already released for research purposes before you withdrew consent, MD Anderson will not be able to destroy them.

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

Circle your choice of "yes" or "no" for each of the following optional procedures:

Optional Procedure #1: Do you agree to allow extra blood drawn to be drawn and stored at a research bank in MD Anderson for use in future research related to cancer and/or other diseases?

YES **NO**

3. COSTS AND COMPENSATION

If you get hurt as a direct result of being on this study, HOPE Clinic will provide medical care for you. However, you are responsible for paying for this care, and you and/or your insurance will be billed for the cost of care. You will not be reimbursed for expenses or compensated financially by MD Anderson or HOPE Clinic for this injury. If you have questions about injuries you receive due to being on this study, you may call the head director (Chair) of MD Anderson's IRB at 713-792-6477 with your questions.

The IRB is a committee of doctors, researchers, and people from the community that is responsible for protecting study participants and making sure all research is safe and ethical.

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.

Samples that are collected from you in this study may be used to develop treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

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

You will be given a $10 gift card at the end of the first study visit. If you have a follow-up visit, you will receive a $20 gift card at the end of the follow-up visit.

If you change your mind and decide not to be in the study, you will only be paid for the visits you completed.

More Information

4. If you have any questions about the study, you may call the study head Dr. Jessica P. Hwang, at 713-745-4516. For questions about your rights as a study participant, you may call the head of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477.

5. If you decide not to be in this study, you can still get care at HOPE Clinic as usual. If you do join the study, but later change your mind, you can drop out at any time. You can still get your usual care at HOPE. Whether you decide to join the study or not, HOPE Clinic staff will treat and provide care for you as usual.

6. This study, or your participation in it, may be changed or stopped without your consent at any time by the study chair (Dr. Hwang), the Cancer Prevention and Research Institute of Texas (CPRIT), or MD Anderson’s IRB.

7. If the doctors learn any information (such as from your test results) that may change your mind about wanting to be in the study, we will tell you about it right away. Then we will ask you again if you still want to be in the study. If you do want to continue with the study, you may be asked to sign the informed consent form again.

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: Cancer Prevention and Research Institute of Texas (CPRIT).

10. 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.

Data

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

If later on we want to share your data with others, to do more research, the researchers must get approval from the MD Anderson IRB before they can use data. If we remove any personal information that can identify you, such as your name, address, and date of birth, we will not need to contact you to get your permission to do the research. If all or some of your personal identifying information is kept attached to your data, the IRB would decide if researchers need to get your permission to use the data.

If the future research is done at MD Anderson, all or some of your personal identifying information may be kept attached to your data. In this case, the researchers must get approval from the MD Anderson IRB before they can use your data. The IRB would decide if researchers need to get your permission to use the data.

If this research is not performed at MD Anderson, MD Anderson will not have oversight. This means they will not be responsible for checking how the data is being used.

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

A. This study is monitored and reviewed by many people to make sure it is done correctly. These people may see personal information about you, such as your name and address. These reviewers include:

- The Office for Human Research Protections (OHRP)
- The IRB and officials of MD Anderson
- Cancer Prevention and Research Institute of Texas (CPRIT), who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study
- The HOPE Clinic staff
- Study monitors and auditors who check to make sure all the information is accurate

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

B. If you decide to take part in this study, you must sign the consent and permission form.

C. State and federal laws require that MD Anderson and HOPE Clinic keep your personal health information (PHI) confidential. However, in some situations, health authorities could require that MD Anderson or HOPE Clinic reveal the names of participants.

If your PHI is shared outside of MD Anderson and HOPE Clinic, it may no longer be protected by federal privacy laws.

D. Researchers have your permission to use your PHI forever, until you say your PHI cannot be used in writing. If you no longer want to let researchers use your PHI, you can take back your permission. If you change your mind about letting researchers use your PHI, you will be removed from this study. No more information will be collected from you. However, the data collected about you up to that point can be used and included in data analysis. If you would like to know more about how to withdraw your permission, you can call MD Anderson's Chief Privacy Officer at 713-745-6636.

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 any 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

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol **2019-0978.**

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

_____
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.)