THE UNIVERSITY OF TEXAS
MD ANDERSON
CANCER CENTER

Informed Consent

UT M.D. Anderson Cancer Center
Institutional Review Board
Approved

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Assessing Problem Areas in Referrals in Chronic Hematologic Malignancies and Developing Interventions to Address Them
DR07-0819

Subtitle: Patients Informed Consent

Study Chair: Lewis E. Foxhall

1. _____ _____
Participant's Name Medical Record Number

You are being asked to take part in this behavioral research study at The University of Texas M. D. Anderson Cancer Center ("M. D. Anderson"). This consent form explains why this research study is being performed and what your role will be if you choose to participate. This form also describes the possible risks connected with being in this study. After reviewing this information with the person responsible for your enrollment, you should know enough to be able to make an informed decision on whether you want to participate in the study.

You are being asked to take part in this study because you have blood cancer (a hematologic malignancy).

DESCRIPTION OF RESEARCH

2. PURPOSE OF STUDY

The goal of this study is to collect information about early referral and treatment for hematologic malignancies from 18 patients.

3. DESCRIPTION OF RESEARCH

Interview
If you agree to take part in this study, you will be asked questions about the process you went through to become an M. D. Anderson patient. You will be asked about the types of doctors you saw and the referrals you were given. You will also be asked about your experiences as an M. D. Anderson patient. No personal identifying information will be collected. This interview will take between 30-45 minutes.

Length of Study
After your interview is finished, your participation on this study is complete.

This is an investigational study. Up to 18 patients will take part in this study. All will be enrolled at M. D. Anderson. There is no cost to you for taking part in this study.
At the end of the interview, you will receive $30 gift card as compensation for your time and effort.

4. RISKS, SIDE EFFECTS, AND DISCOMFORTS TO PARTICIPANTS

The interview may discuss topics that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. You may choose to end the interview at any time.

This research study may involve unpredictable risks to the participants.

5. POTENTIAL BENEFITS

Your answers may help researchers learn how to give doctors the information they need to better help their patients. The results of this study may lead to programs that may help with diagnosing and referring patients with blood cancers. Future patients may benefit from what is learned. There are no benefits for you in this study.

6. ALTERNATE PROCEDURES OR TREATMENTS

You may choose not to take part in this study.

I understand that the following statements about this study are true:

7. My participation in this research study is strictly voluntary.
8. I may ask any questions I have about this study, including financial considerations, of the study chair. I may contact the study chair, Dr. Lewis E. Foxhall, at 713-792-2202. I may also contact the Chairman of M. D. Anderson's Institutional Review Board (IRB) at 713-792-2933 with any questions that have to do with this study or my rights as a study participant.
9. M. D. Anderson will take appropriate steps to keep my personal information private. However, there is no guarantee of absolute privacy. The U.S. Food and Drug Administration (FDA) and the IRB of M. D. Anderson might review my record to collect data or to see that the research is being done safely and correctly. Under certain circumstances, the FDA could be required to reveal the names of participants.
10. If I suffer injury as a direct result of participation in this study, M. D. Anderson will provide medical care. However, this medical care will be billed to my insurance or me in the ordinary manner. I understand that I will not be offered reimbursement of expenses or financial compensation from M. D. Anderson for this injury. I may also contact the Chairman of M. D. Anderson's IRB at 713-792-2933 with questions about study-related injuries.
11. Certain tests, procedures, and/or medications that I may receive as part of this study may be free to me because they are for research purposes only. However, my insurer or I may be financially responsible for the cost of supportive care and treatment of any complications resulting from the research tests, procedures, and/or medications, such as hospitalization, nausea, vomiting, low blood cell counts, and dehydration. Standard medical care that I receive under this research study will be billed to my insurer and/or me in the ordinary manner. I should learn before participating in this study which part of the research-related care will be free, which costs my insurer will pay for, and which costs will be my responsibility.
12. I understand that there are no plans to provide any compensation to me for any patents or discoveries that may result from my participation in this research.

Authorization for Use and Disclosure of Protected Health Information:

A. The research team at M. D. Anderson will be collecting information about you that they may share with laboratory researchers that use the samples collected from you. This information may include your medical history, treatment schedule and the results of any tests, therapies, and/or procedures that you may go through. The purpose of collecting and sharing this information is to help researchers to link their laboratory findings with clinical information and/or outcome data in an effort to learn about referral patterns in hematologic malignancies and how to improve therapy for N/A. N/A will receive the research samples.

   You have the right to see and reproduce your records related to the research study for as long as this information is held by the study chair or M. D. Anderson. However, in some studies, in order to ensure the scientific value of the study, participants are not able to view or reproduce their study records until the research has been completed with all participants in the study.

B. There is no expiration date for the use of this information as stated in this authorization. You may withdraw your authorization to share your personal health information at any time in writing. Instructions on how to do this can be found in the M. D. Anderson Notice of Privacy Practices (NPP). You may contact the Office of Protocol Research at 713-792-2933 with questions about how to find the NPP. If you withdraw your authorization, you will be removed from the study, and the study chair and staff will no longer use or disclose your personal health information in connection with this study, unless the study chair or staff needs to use or disclose some of your research-related personal health information to preserve the scientific value of the study. M. D. Anderson may use any study data that were collected before you canceled your authorization.

C. If you refuse to provide your authorization to disclose your protected health information, you will not be able to participate in this research project.

D. Your personal health information will be protected according to state and federal law. However, there is no guarantee that your information will remain confidential, and it may be re-disclosed at some point.

CONSENT/AUTHORIZATION

Having read and understood the above and having had the chance to ask questions about this study and reflect and consult 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 have been given a signed copy of this consent.

SIGNATURE OF PARTICIPANT _____ DATE _____

I was present during the explanation of the research to be performed under Protocol **DR07-0819**.

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

SIGNATURE OF PERSON RESPONSIBLE & RELATIONSHIP _____ DATE _____

I have discussed this behavioral research study with the participant and/or his or her authorized representative, using a 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.

SIGNATURE OF STUDY CHAIR OR PERSON OBTAINING CONSENT _____ DATE _____

Translator

I have translated the above informed consent into _____ and assisted the study chair in the consenting process (Name of Language) for this participant.

NAME OF TRANSLATOR _____ SIGNATURE OF TRANSLATOR _____ DATE _____