THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

Consent Revision Date: 11/18/2005

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Collection of Outcomes Data for Pregnant Patients with Cancer
2005-0518

Study Chair: Andrea Milbourne

1.

Participant's Name _____ Medical Record Number _____

You are being asked to take part in this observational 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 your are pregnant or have been pregnant while diagnosed with cancer.

DESCRIPTION OF RESEARCH

2. PURPOSE OF STUDY

The goal of this research study is to collect information on patients who are or were pregnant while diagnosed with cancer and to store this information in a research database.

3. DESCRIPTION OF RESEARCH

If you agree to take part in this study, information about the type of cancer, the type of treatment you have had or are having, and details about your pregnancy will be collected for the database. Data will be collected from patients seen at M. D. Anderson since September 2003 until data has been collected for 200 cases. This study may be completed as soon as 2010 based on the number of pregnant patients we have seen in the last 15 months. This information will serve as a basis for future studies about pregnant women with cancer. You will receive no special tests or treatment at M. D. Anderson as a result of this study.

Progress notes and ultrasound reports about your pregnancy will be requested from UT Maternal Fetal Medicine and/or from your personal obstetrician. This information will be entered into the database and also included in your medical record. If the information is not consistent in the record, we may contact you to clarify the information. You will remain on study until your pregnancy and/or any treatment you are receiving are completed.

Once a year the database will be updated to include information about patient survival. This information is usually found in the medical record however it may be necessary to contact you directly.

This is an investigational study. There will be no cost for participating in this research study. About 200 patients will take part in this study. All will be enrolled at M. D. Anderson.

4. RISKS, SIDE EFFECTS, AND DISCOMFORTS TO PARTICIPANTS

There are no expected physical risks, side effects or discomforts to you in this study. M. D. Anderson will make reasonable efforts to preserve your privacy but cannot ensure complete privacy.

This research study may involve unpredictable risks to the participants.

5. POTENTIAL BENEFITS

This database may lead to improvements in how doctors care for pregnant patients in the future. There may be no benefits for you in this study.

6. ALTERNATE PROCEDURES OR TREATMENTS

You may choose not to take part in this study. Refusal to take part in this study will not affect care for your pregnancy or your cancer or cause penalty or loss of benefits to which you are otherwise entitled.

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

7. As required by the M. D. Anderson conflict of interest policy, a faculty member may not serve as the study chair for a study or primary physician for a subject on a study if he or she or a family member holds any equity interest in the company sponsoring the study or has received cash in excess of $10,000 within the previous 12-month period from the company.
8. If I want to receive updated information regarding the financial interests of any researchers on this study, I may call the Conflict of Interest Coordinator at 713-792-3220. Upon request, I will be given access to information disclosing the identity of all investigators who have a financial interest in the sponsor or supporter of this study.
9. My participation in this research study is strictly voluntary.
10. I may ask any questions I have about this study, including financial considerations, of the study chair. I may contact the study chair for this study, Dr. Andrea Milbourne at 713-745-6986 or the Chairman of the 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.
11. I may withdraw at any time without any penalty or loss of benefits.
12. I understand that the study may be changed or stopped at any time by the study chair or the IRB of M. D. Anderson.
13. I will be informed of any new findings that might affect my willingness to continue participating in the study.
14. M. D. Anderson will take appropriate steps to keep my personal information private. However, there is no guarantee of absolute privacy. Health authorities 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, health authorities could be required to reveal the names of participants.
15. 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 receive reimbursement of expenses or financial compensation from M. D. Anderson or the manufacturer 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.
16. Unless otherwise stated in this consent form, all of the costs linked with this study, which are not covered by other payers (HMO, Health Insurance company, etc.), will be my responsibility.
17. 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. During the course of this study, the research team at M. D. Anderson will be collecting information about you that they may share with health authorities.

   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, to ensure the scientific value of the study, participants are not able to view and reproduce their study records until the research has been completed on all participants in the study. If possible for this study, your doctor will be able to discuss your clinical test results with you.

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 this protected health information, you will not be able to participate in the research project.

D. You understand that 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, 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 copy of this consent.

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

SIGNATURE OF PARTICIPANT DATE

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

WITNESS OTHER THAN PHYSICIAN OR INVESTIGATOR DATE

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

SIGNATURE OF PERSON RESPONSIBLE & RELATIONSHIP DATE

I have discussed this observational 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.

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

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.

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

NAME OF TRANSLATOR | SIGNATURE OF TRANSLATOR | DATE