An Intervention to Improve Decision Role Concordance

amongst Newly Diagnosed Breast Cancer Patients

Patient Consent Form

The University of Utah IRB #:
00081898

Jan 29, 2017

Consent and Authorization Document

for Minimal Risk Research

BACKGROUND

You are being asked to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you want to volunteer to take part in this study. Participation in this study is not required for you to obtain standard treatment.

You are being asked to participate because you are seeing a breast surgeon for a consultation. Many patients prefer to have an active role in the decisions they make with regards to the type of surgery they are having. While there is no standard, physicians prefer each patient-doctor interaction to be both informative and one of a shared decision making process. Different patients prefer different roles and this study will help us understand the desired role patients prefer when they visit with the doctor.

STUDY PROCEDURE

If you decide to participate in this study, you will be required to complete five short surveys as well as agree to have your consultation audio recorded. These surveys will be given at different times during this study and none of them should take very long to fill out. The first survey you will fill out is the Patient Preference Scale and it will ask you how you prefer to make medical decisions. There are five options and you circle the one that most closely describes you. This will be filled out prior to your visit with your surgeon. You will also be asked to fill out the FACT-B survey. This survey has 37 questions and asks about your current well-being and concerns that you have about your breast cancer. You will then have your appointment as originally planned and the survey should not interfere with your appointment as you will take it while waiting for your doctor. Your entire visit with your doctor will then be audio recorded. Once your appointment is over you will then take the second survey, the Patient Perception Scale. This survey will ask about decisions made during your appointment. Again it is a one question survey in which you circle the option that best describes your feelings. You will also be asked to fill out a six question survey called the Modified Satisfaction with Decision survey that asks how you feel about the decision making process. Two to six weeks later, you will be contacted to again complete the FACT-B survey and a five question survey called the Decision Regret Scale that asks if you think the decision made was right for you. Six months later, you will be contacted and asked to fill out these same two surveys (FACT-B and Decision Regret Scale). We will then analyze the data and review the audio tapes. These will be transcribed and evaluated. Your physician will also complete a different survey at the time of your appointment.

There are two different groups participating in this study. Patients will be randomized to one of two groups and you will have an equal chance of being in either group. A computer decides the group you will be assigned to. The groups consist of 50 patients in each group. One group will fill out the first survey and the doctor will be informed of your answer. The visit will proceed as normal. The second group will fill out the same survey but the doctor will not be informed of your answers.

By informing the doctor of the role patients prefer to play in health care decisions, we hope patients will have a more positive experience and contribute to a shared decision making consultation. We will compare the Patient Perception Scale (second survey) of both groups and analyze the data to determine if informing the doctor of the role you want to play has an impact on how patients perceive the appointment.

RISKS
The risks of this study are minimal. You may feel upset thinking about or talking about personal information related to breast and anxiety. These risks are similar to this you experience when discussing personal information. If you feel upset from this experience please tell the research staff and we will tell you about resources available to help. There is also a risk in breach of confidentiality of your protected health information. We will store all data on a password protected computer and in locked cabinets.

BENEFITS
There are no direct benefits to you for taking part in this study. However, the information we obtain from this study should help women and their doctors make better, more informed decisions regarding surgical decision making. It could also help doctors understand patient's needs better.

ALTERNATIVE PROCEDURES
If you do not want to take part in the study you will have your regularly scheduled appointment as planned.

PERSON TO CONTACT
If you have questions, complaints or concerns about this study you can contact Dr Cindy Matsen at 801-581-2304. I f you feel you have been harmed by participating in this clinical trial please contact the study coordinator Jingsong Zhao at 801-213-5779 during the hours of 8 am to 5 pm or you can call the hospital operator and have Dr. Matsen paged.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

VOLUNTARY PARTICIPATION
Your participation in this study is voluntary. You do not have to participate and it will not affect the care you receive at our institution. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

COSTS AND COMPENSATION TO PARTICIPANTS
There are no costs nor compensation for participation in this study.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your health for this research study.

This is the information we will use and include in our research records

- Name
- Age
- Where you live
- Past Medical History
- Past Surgical History
- Family medical history
- Allergies
- Current and past medications or therapies
- Information from your imaging exams such as mammograms, ultrasounds, and MRI
- Information about your breast cancer tissue such as biopsies and surgery pathology report
- Information from a physical examination, such as blood pressure reading, heart rate, breathing rate, temperature, and breast and lymph node exam
- All other tests and procedures that will be performed in the study
- Information about your breast surgery
- Information about your other breast cancer treatments such as radiation and chemotherapy

How we will protect and share your information:

We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:

- Members of the research team at Huntsman Cancer Institute and the University of Utah hospital.

- The University of Utah Institutional Review Board (IRB), who reviews research involving people to make sure the study protects your rights;

- The National Institute of Health, the agency funding this study

If we share your identifying information with groups outside of University of Utah Health Sciences Center, they may not be required to follow the same federal privacy laws that we follow. They may also share your information again with others not described in this form.

If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at Huntsman Cancer Institute and the University of Utah Hospital

What if I decide to Not Participate after I sign the Consent and Authorization Form?

You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.
This authorization does not have an expiration date.
You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished.

CONSENT:

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

I agree to participate in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

_____
Participant's Name

_____ _____
Participant's Signature Date

_____
Name of Person Obtaining Authorization and Consent

_____ _____

Signature of Person Obtaining Authorization and Consent Date