

**Patient Centered Communication Model  
Phase II**

**Introduction**

You are being invited to take part in a research study. The information in this form is provided to help you decide whether or not to take part. Study personnel will be available to answer your questions and provide additional information. If you decide to take part in the study, you will be asked to sign this consent form. A copy of this form will be given to you.

**What is the purpose of this research study?**

Often, cases of cancer are detected in advanced stages, resulting in increased levels of psychological distress and anxiety. When information is provided to cancer patients, the following benefits may occur: increased patient involvement in decision-making; greater satisfaction with treatment choices; improved ability to cope during the diagnosis, treatment and post-treatment phases; reductions in anxiety and mood disturbances; and improved communication with family members. Considering the short time period between diagnosis and treatment initiation, it is critical that patients are provided the tools to navigate a healthcare system, be informed about their care, and manage emotional distress. Given the importance of patient-centered communication (PCC), our goal is to develop a computer system that will provide support and guidance to female cancer patients, with the aim of easing levels of anxiety and psychological unrest.

The objectives for the second phase of this study are to develop a PCC model specifically designed for women with breast or gynecological cancer via:

- Groups interviews with patients, caregivers, support group leaders, and promotoras
- Structured interviews with providers
- Evaluation of prototype in terms of usability and usefulness from patients, caregivers, support group leaders and promotoras

**Why are you being asked to participate?**

You are invited to participate because you are a breast or a gynecological cancer patient or you are someone who has direct contact with these patients as a caregiver, promotora or member of a female cancer support group. You are also being asked to participate because you are over the age of 21 years.

**How many people will be asked to participate in this study?**

Approximately 36 individuals will be asked to participate in this part of the study.

**What will happen during this study?**

You will be asked to participate in a 60-minute group interview to discuss preferred computer features for the patient-centered communication model. You will be asked to discuss information which you would consider useful on a communication model, as well as the desirable layout of the model.

**How long will I be in this study?**

We estimate that the group interview will take an hour so you will be required to stay for this length of time to complete participation.

**Are there any risks to me?**

There are no known risks from your participation and no direct benefit from your participation is expected. You may withdraw from the study at any time without any prejudice. There is no cost to you except your time.

**Are there any benefits to me?**

You may not receive any benefit from your participation and we cannot guarantee direct benefit to you from your participation. You may withdraw from the study at any time without prejudice.

**Will there be any costs to me?**

Aside from your time, there are *no costs* for taking part in the study.

**Will I be paid to participate in the study?**

You receive a check for \$20 upon completion of the study. This is to compensate you for time spent, travel, and miscellaneous expenses related to the interview.

**Will video or audio recordings be made of me during the study?**

An audio recording will be conducted during the group interview. To be certain that your responses are recorded accurately please check the box below:

- I give my permission for audio recordings to be made of me during my participation in this research study.
  
- I do not give my permission for audio recordings to be made of me during my participation in this research study.

**Will the information that is obtained from me be kept confidential?**

The only persons who will know that you participated in this study will be the research Principal Investigator and research personnel.

Your records will be kept private under the Privacy Act. You will not be identified in any reports or publications resulting from the study. Representatives of regulatory agencies including Sterling IRB may access your records.

**What if I am harmed by the study procedures?**

This project involves minimal risks to study participants, so no precautions are necessary.

**May I change my mind about participating?**

Your participation in this study is voluntary. You may decide to not begin or to stop the study at any time. Your refusing to participate will have no effect on your medical status or your relationship with your health care professionals. You can discontinue your participation with no effect on your employment status or professional relationship with the research team. Any new information discovered about the research will be provided to you.

**Whom can I contact for additional information?**

You can call the Principal Investigator to tell him/her about a concern or complaint about this research study. The Principal Investigator, DerShung Yang, Ph.D., can be called at (847) 419-9288 or the Project Manager, Niina Haas, M.A., at (480) 329-1889. If you have questions about your rights as a research subject you may call Sterling IRB at (888) 636-1062.

**Your Signature**

By signing this form, I affirm that I have read the information contained in the form, that the study has been explained to me, that my questions have been answered and that I agree to take part in this study. I do not give up any of my legal rights by signing this form.

\_\_\_\_\_  
Name (Printed)

\_\_\_\_\_  
Participant's Signature

\_\_\_\_\_  
Date signed

**Statement by person obtaining consent**

I certify that I have explained the research study to the person who has agreed to participate, and that he or she has been informed of the purpose, the procedures, the possible risks and potential benefits associated with participation in this study. Any questions raised have been answered to the participant's satisfaction.

\_\_\_\_\_  
Name of study personnel

\_\_\_\_\_  
Study personnel Signature

\_\_\_\_\_  
Date signed