

Attachment 9: Informed Consent for Patients

BrightOutcome Symptom Management System: Usability Test

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?

This study will help to determine the general usability of the tested prototype. More specifically, the study will isolate design inconsistencies and usability problem areas within the user interface and content areas.

Why are you being asked to participate?

You are being invited because you are or have been a cancer patient.

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

Up to 20 persons will be asked to participate in this study.

What will happen during this study?

Users will be asked to perform key tasks, locate key information, navigate from screen-to-screen and find help and support. Additional information will be evaluated pertaining to the visual and aesthetic design as it supports the key tasks.

How long will I be in this study?

We will need approximately sixty minutes of your time to complete the interview.

Are there any risks to me?

The questions that we ask pose no risk to you. However, if you would prefer not to answer a particular question, you may decline to answer it, and you can stop participating at any time. You can ask that any information you give us be kept secure; you also can ask that we cease recording information as well.

Are there any benefits to me?

You will not receive any direct benefit from taking part in this study. However, in the long run, this research will help to create a usable and useful tool for administering care to cancer patients.

What are the alternatives for participating in this study?

The alternative is not to participate in this study.

Will there be any costs to me?

There will be no monetary costs to the participants. The only cost to the participants is the time of approximately 60 minutes.

Will I be paid to participate in the study?

You will be compensated \$40 for your time spent, travel, and miscellaneous expenses related to the usability testing.

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

We will make an audio recording during the study so that we can be certain that your responses are recorded accurately only if you check the first box below.

I give my permission for audio/video recordings to be made of me during my participation in this research study.

I do not give my permission for audio/video 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 secure to the extent provided by law. 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.

Anything you ask to keep secure will be stricken from any written transcript of audiotapes, and will be kept in a separate notes file with no personally identifying information. You can make this request at any time during the interview, or after the interview via phone or email. The final report, subsequent proposal, or any other written material will not include transcripts or notes from the interviews.

Are there risks for participating in this study?

There is only minimal risk from taking part in this study.

May I change my mind about participating?

Your participation in this study is voluntary. You may decide to not begin or to stop participation at any time, without any consequences for you. Also any new information discovered about the research will be provided to you. This information could affect your willingness to continue your participation.

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