INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR

Increasing Colorectal and Breast Cancer Screening in Women

STUDY PURPOSE

The purpose of this study is to find the best way to get women to have regular colorectal and breast cancer screenings. A woman can be in the study if: 1) if she is a patient of one of our participating doctors, 2) if she is between the ages of 50 -75, 3) if she has not had regular colorectal cancer screenings, 4) if she has not had colorectal cancer or related diseases, 5) does not have any health problems that would prohibit a mammogram or colorectal cancer screening test, and 6) has access to high speed internet.

NUMBER OF PEOPLE TAKING PART IN THE STUDY:

If you agree to participate, you will be one of 1588 women who will be participating in this research.

PROCEDURES FOR THE STUDY:

If you agree to be in the study, you will do the following things:

You will be asked to complete a survey by telephone or Web (which ever you prefer) three times over a period of about six months which includes questions about your beliefs, knowledge, and experience with breast and colon cancer screening. The data will be transferred to a secure computer database and identification information will be removed before running any analysis. These surveys will occur at the beginning of the study, about 4 weeks after entering the study, and again at 6 months. If you are doing a telephone interview, we may ask you if it is alright to audiotape the call for quality assurance. If you do not want the call to be audiotaped, this will not affect your participation.

You also will be randomly assigned to a group that gets either a Web-based program to view on a computer, a telephone counseling call, both a Web-based program and phone counseling call, or a group that only gets a telephone call. If you are put in the Web-based program group, we will ask you to login to a website that we give you and view a program. The program will take about 30 minutes to watch. If you are in the phone counseling group, a counselor will schedule a phone call which will take about 15 minutes. You may also be in a group that would get both a Web program and a phone counseling call.

RISKS OF TAKING PART IN THE STUDY:

There will be no physical risk to you in this study. You may refuse to participate in the study or drop out at any time. Your participation in the study will not affect your medical care. All information will be held on a secure computer and we take multiple steps to ensure confidentiality, however, there is always a chance that identifiable information could illegally be accessed by someone outside of our research team. If you experience uncomfortable feelings when talking about breast cancer or colorectal cancer, trained graduate students will talk to you about these feelings. If you would like to speak to someone else, you may call Dr. Victoria L. Champion's research office at (866) 434-0116.

BENEFITS OF TAKING PART IN THE STUDY:

The benefits of being in the study include getting information about colorectal and breast cancer screening and information on colorectal and breast health. Being in the study will also help us understand the best way to provide information to women about caring for their colorectal and breast health.

ALTERNATIVES TO TAKING PART IN THE STUDY:

Instead of being in the study, you may choose not to take part in the study. Choosing not to join the study will not affect the care you receive from your doctor or your insurance plan in any way.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. We cannot guarantee confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published. If tape recordings are made of any of the phone calls, only the researchers working on this study will have them. Any tape recordings will be destroyed after the recorded conversation has been typed.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the IU Institutional Review Board or its designees, the study sponsor, National Institutes of Health, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP) who may need to access your medical and/or research records.

COSTS

There is no cost to you or your insurance company for taking part in this study.

PAYMENT

For taking part in this study, you will receive a $20 gift card for each survey you complete, for a total value of $60 if you complete all three surveys.

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study or a research-related injury, or to obtain information or offer input, contact the researcher Dr. Victoria Champion at (866) 434-0116. If you have questions about your rights as a research participant or to discuss problems, complaints or concerns about the study, please call the IU Human Subjects Office at (317) 278-3458 or (800) 696-2949.

VOLUNTARY NATURE OF STUDY

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with Indiana University School of Nursing or partners in this study.

CONSENT

If you agree to participate, you will be given a copy of this informed consent document to keep. We will also ask you to let us access your medical records for information about cancer screening tests and you will need to complete a short form to grant this permission.

In consideration of all that you read in the letter mailed to you, OR in consideration of all that you have heard today, do you give your consent to participate in this research study?

<1> Yes
<9> RF