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University of South Dakota

Department of Social Work

Intervention To Promote Breast Cancer Screening Among American Indian Women

Informed Consent Form for Control Group

Date of Document: 10/01/2021

INFORMED CONSENT – Control Group
The University of South Dakota

TITLE: Intervention to Promote Breast Cancer Screening Among American Indian Women
PROJECT DIRECTOR: Soonhee Roh, PhD
PHONE #: (605) 357-1593
Department: Social Work

Invitation to be Part of a Research Study

You are invited to participate in a research study. Eligibility criteria include those: (1) who are self-identified American Indian women of the Yankton Sioux Tribe in South Dakota, (2) who are aged 40 to 70 years, (3) who have not received a mammogram in the past two years, and (4) who are willing to use their own mobile phone, iPad, tablets, and computers, or a mobile phone borrowed from the research team. Taking part in this research project is voluntary. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

The purpose of the study is to develop and evaluate the Mobile Web App Breast Cancer Screening (called wMammogram) that is culturally tailored for American Indian women.

What will happen if you take part in this study?

You are participating in a control group in this study. You will receive the mailing of printed educational materials, including a brochure with information on breast cancer and relevant screening guidelines from the American Cancer Society, a list of community clinics that offers low-cost or free mammography, as well as contact information of the health navigator for further assistance. There will be two surveys: one at the beginning and one a week the intervention (the mailing). We will ask if you have scheduled a doctor appointment to get screened for breast cancer, which is called a mammogram. We will ask you this after the 7-day period and again 6 months later. We will also ask you questions about breast cancer knowledge, health beliefs, cultural attitudes, and your intent to undergo screening. We will also ask you health-related questions including your knowledge about Alzheimer's, Dementia, Mental Health and Wellbeing, Opioid Overdose and we will be collecting demographic information.. These interview questions will take about 20-30 minutes to answer in person. Six months after the second survey, there will be a 2-hour focus group.

Your Participation in this Study is Voluntary

It is up to you to decide to be in this research study. Participating in this study is voluntary. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer. You may refuse to participate or choose to discontinue participation at any time without losing any benefits to which you are otherwise entitled.

What risks might result from being in this study?

There are no risks in participating in this research beyond those experienced in everyday life. If you find some of the questions to be sensitive in nature or experience emotional discomfort, you can reach out to a licensed counselor at the Helpline Center (1-800-273-8255).

How could you benefit from this study?

Although you will not directly benefit from being in this study, we hope to positively impact clinical and public health practice through developing an innovative health intervention that builds upon low cost technology and enhances accessibility and sustainability of preventive care to help reduce health disparities experienced by Native Americans.

How will we protect your information?

The records of this study will be kept confidential to the extent permitted by law. The survey does not ask for any information that would identify who the responses belong to (e.g., it does not ask for your name). Your name or other identifying information will not be stored with the data, which will be saved on the University of South Dakota, School of Health Science, Department of Social Work server. The server is password protected and only Dr. Soonhee Roh will have access to the data. The code key linking your name to name or other identifying information about you will be kept in a separate, secure location. Information contained in your records will not be given to anyone unaffiliated with the research team. Your name or other identifying information will not be used in any publication or teaching without your specific permission.

Since other people will be present at the focus group, we cannot guarantee what you say will be kept confidential. We encourage you to not reveal any identifying information about yourself or others, or to repeat anything that is said during the focus group afterwards. The focus group will be audio recorded, but the recordings will be transcribed without identifying information and then deleted. You are free request to view and edit the transcriptions.

The audio tapes, research data, and personal information of participants in this study will be kept in locked filing cabinets which will be secured by the researcher. Only the researcher will have access to this information. If the results of the research are published or discussed at conferences, no information will be included that would reveal your identity. The transcriptions, and de-identified research data will be kept for 3 years for subsequent research and then will be destroyed.

It is possible that other people may need to see the information we collect about you. These people work for the University of South Dakota and other agencies as required by law or allowed by federal regulations.

How will we compensate you for being part of the study?

- If you participate in the control group, you will complete two surveys and will receive $20 cash (including $10 for the first survey and $10 for the second survey one week after the intervention).
- Also, as appreciation of your time and travel costs, all participants will be given $20 cash at the second survey date.
- After 6 months from the second survey, there will be a face to face interview survey ($10) and 2-hour focus group which will pay $50 to all those who participate.

Will you have any costs for participating in this study?

You may have travel expenses for driving to and from the interviews and focus groups. To show our appreciation, you will be compensated the amounts stated in the previous section.

Who is funding this research?

The National Institutes of Health (a federal agency) and the University of South Dakota is funding this research.

Contact Information for the Study Team and Questions about the Research

The researcher conducting this study is Soonhee Roh, PhD. You may ask any questions you have now. If you later have questions, concerns, or complaints about the research please contact Dr. Soonhee Roh at (605) 357-1593 during the day.

If you have questions regarding your rights as a research subject, you may contact The University of South Dakota—Office of Human Subjects Protection at (605) 658-3767. You may also call this number with problems, complaints, or concerns about the research. Please call this number if you cannot reach research staff, or you wish to talk with someone who is an informed individual who is independent of the research team.

Your Consent

Before agreeing to be part of the research, please be sure that you understand what the study is about. We will give you a copy of this document for your records.

I understand that by signing below, I volunteer to participate in this research. I understand that I am not waiving any legal rights. I have been provided with a copy of this consent form. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation.

Subject's Name: _____

_____ _____

Signature of Subject Date