INFORMED CONSENT
The University of South Dakota

TITLE: Intervention to Promote Breast Cancer Screening Among American Indian Women
PROJECT DIRECTOR: Soonhee Roh, PhD
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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 study is voluntary. Please take time to read this entire form and ask questions before deciding whether to participate in this research project.

The purpose of the study is to develop and evaluate the mobile web app breast cancer screening tool wMammogram that is culturally tailored for American Indian women.

What will happen if you take part in this study?

This study has two parts. In the first part, you will be asked to answer questions in a two-hour face-to-face focus group interview. The group will consist of tribal community leaders/members and local health care professionals with backgrounds in cancer and health management. Questions will cover the following topics: (1) knowledge, beliefs, perceptions, and attitudes about breast cancer and breast cancer screening; (2) individual, structural, and cultural barriers to screening; (3) perceptions about mobile web app intervention approaches; (4) current mobile phone usage habits, including text and picture messaging, SMS and MMS subscriptions; and (5) suggestions regarding the most effective content, type, and frequency of messages to appeal to American Indian women.

In the second part, the intervention, you will use the phone app wMammogram for seven days. After this intervention, there will be 3 interviews and a focus group: one interview at the beginning, one interview a week after the intervention, one interview six months after the intervention, and a post-intervention focus group. We will ask if you have scheduled a doctors appointment to get a mammogram to be screened for breast cancer. We will ask you this a week after the intervention and again 6 months later. We will also ask you questions about your breast cancer knowledge, health beliefs, cultural attitudes, and intent to undergo screening. We will also ask you other 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 30 minutes to answer in person. Focus group participation will take about 2 hours.

If you do not have a cell phone, the research team will lend you one to use. It must be returned when the study is over. The phone will have one-month worth of service/available data and may only be used for this research study. It may not be used for personal use. If you stop participating, the phone must be returned. If something happens to this phone, we may end your participation in this study.

Your Participation in this Study is Voluntary

Participating in this study is voluntary. Even if you decide to be part of the study now, you may change your mind. 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 study 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 research study, we hope to positively impact clinical and public health practice by 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 American women.

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 identifiable information (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 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 groups, 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 groups afterward. The focus groups 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 research team. Only the research team will have access to this information. If the results of the research study 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 7-day intervention group, you will be given up to a total of $100 cash for your time (including $10 for the pre-test; $70 for the 7-day intervention; $10 for the post-test; and $10 cash for the intervention quiz rewards). Cellphone/other data usage will be reimbursed with $65 cash after the intervention.
- Also, as an appreciation of your time and travel costs, all participants will be given $20 cash at the post-test date.
- After 6 months from the post-test, there will be a face to face survey interview ($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. For those who drive over 50 miles, will be reimbursed 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 study.

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 study 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 study. Please call this number if you cannot reach the 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 study, 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 study. 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.

I give consent for my quotes to be used in the research study; however, I <u>will not</u> be identified.
Please initial: ____ *Yes* ____ *No*

Subject's Name: _____

_____ _____
Signature of Subject Date