IRB CODE NUMBER: 2019.053

NCT number: 05530603

University of South Dakota

Department of Social Work

Intervention To Promote Breast Cancer Screening Among American Indian Women

Study Protocol

Date of Document: 05/02/2022

UNIVERSITY OF SOUTH DAKOTA

Office Use Only
Date Received:
Protocol Number

Non-Medical IRB Submission Form

Submit one copy of the application and required materials to humansubjects@usd.edu. The signature page may be emailed or delivered to Slagle 107. **Studies not will be approved until we have received the signature page.**

Today's Date:

08/7/2019

Project Title:

Intervention to Promote Breast Cancer Screening Among American Indian Women

Note: A student's advisor is considered the "Principal Investigator" and has ultimate responsibility for the conduct of the student(s).

Principal Investigator: Soonhee Roh, PhD
Department: **Social Work** email: **Soonhee.Roh@usd.edu** phone: **605-357-1593**
Qualifications to do the research: **Principal Investigator**
CITI Date: **10 May 2019 CITI is good for 3 years from the completion date. (2 years for VA employees)**

Other Investigator:
Department: email: phone: Role in Study: CITI Date:

Other Investigator:
Department: email: phone: Role in Study: CITI Date:

Other Investigator:
Department: email: phone: Role in Study: CITI Date:

Other Investigator:
Department: email: phone: Role in Study: CITI Date:

FOR VA STUDIES

Has this application been approved by the ISO and Privacy Officer?

☐ Yes - Please attach a copy of their approval with signature page.
☐ No - **Do not submit application to IRB until approval has been received.**

Section 1: General Questions

1. Do you or any of the investigators have a potential conflict of interest associated with this study?
   ☐ Yes: Fill out and attach a Disclosure Form B (Disclosure of Financial Interests)
   ☒ No

2. Is this study **externally** funded? (**If yes, please attach a copy for each one selected**)
   ☐ No
   ☒ Federally Sponsored Project-pending
   ☐ Industry Sponsored Study
   ☐ State Sponsored Project

3. If this project is for a student to complete their thesis or dissertation, has it been approved by the dissertation or thesis committee?
   ☒ N/A ☐ Yes
   ☐ No **DO NOT submit an application until approval is granted**

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4. Have you, or do you, plan to submit this study to another IRB?
   - ☒ Yes – please submit a copy of the IRB decision and approved consent/assent.
   - ☐ No

5. What is the purpose of your research? The purpose of this study are to develop and evaluate the feasibility and effectiveness of the Mobile Web App Breast Cancer Screening (wMammogram) intervention that is culturally tailored for American Indian (AI) women.

6. From the beginning, being the initial contact of participant(s) through last contact with participant(s) please describe the task(s) they will be expected to perform. (How will you contact them? What will you have them do?) The proposed study addresses two specific aims with a multi-method, two-phase research project that will take place in South Dakota over a three-year period. The two phases are: (1) developing the wMammogram intervention (Aim 1) and (2) evaluating the feasibility and efficacy of the wMammogram (Aim 2). Phase 1 incorporates a Community Based Participatory Research (CBPR) approach and a series of focus groups with various stakeholders in AI communities to design a culturally informed and practically refined intervention. Phase 2 uses a randomized clinical trial (RCT) design with AI women. In phase one, after the approval of the Yankton Tribal Institutional Review Board (IRB), Dr. Roh will convene two focus groups (N=20; n=10 for each group). Each group will consist of AI community leaders/members and local health professionals with backgrounds in cancer and health management. The purpose of the two focus groups will be to obtain firsthand information about the general public/health care professionals' beliefs, attitudes, and values about breast cancer and screening, as well as barriers, motivators, and possible triggers for screening. In phase two, the wMammogram intervention will be implemented with AI women using the blinded RCT over a seven-day period. Assessments with a mixed methods approach will be conducted at three intervals: baseline, one-week post-intervention, six-month follow-up survey, and post-intervention focus group.

7. Have you attached letters of approval from any schools or businesses involved?
   - ☐ Yes
   - ☒ N/A

Section 2: Participants

8. Please state the maximum number of participants you plan on enrolling. **107**

9. Please describe the study populations by checking all that apply.
   - ☐ Males
   - ☒ Females
   - ☐ University Students
   - ☐ Non-English Speaking
   - ☐ Students in Grades K-12

10. Are you **specifically** targeting an ethnic group? Check any that apply.
    - ☒ American Indian
    - ☐ African American
    - ☐ Caucasian
    - ☐ Alaskan Native
    - ☐ Asian
    - ☐ Pacific Islander
    - ☐ Hispanic
    - ☐ Other

11. Age ranges of subjects to be enrolled?
    - ☐ Birth-3
    - ☐ Preschool 3-5
    - ☐ Elementary 5-10
    - ☐ Middle School 10-13
    - ☐ High School 14-17
    - ☒ Adult 18 and 64
    - ☒ Senior Citizens 64 and up

12. Please state any inclusionary and exclusionary criteria and how will the participants be screened. Eligibility criteria include those: (1) who are self-identified AI women, (2) who are aged 40 to 70 years, (3) who have not received a mammogram in the past two years, (4) who live in South Dakota, (5) who are willing to possess an active email account, and (6) who are willing to use their own mobile phone or a mobile phone borrowed from the research team for the wMammogram intervention. The participant age range of 40-70 was selected based on the breast cancer screening guidelines of the American Cancer Society (ACS) that recommend women to begin regular mammograms at age 40.47 The exclusion criteria include those who (1) are minors (under 18 years), (2) received a mammogram in the past year, and (3) are under 40 or over 70 years of age.

13. Are any of the vulnerable populations listed below going to be enrolled in this study?

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- ☐ Your employees
- ☐ Your students
- ☐ Prisoners
- ☐ Children
- ☐ Individuals with diminished mental/physical capacity
- ☐ Pregnant women
- ☐ Economically/educationally disadvantaged persons

14. Are the research participants your students or employees?
    - ☒ No
    - ☐ Yes – explain how you plan on avoiding your student(s) feeling or perceiving undue influence for participation

15. Where will the research take place? Yankton Sioux Tribe

16. If this research is taking place in a classroom, describe what non-participants will do during the research (activities and supervisions). Students not participating in the research should not be singled out or penalized. N/A

17. Will the participant(s) receive any compensation or extra credit? If so please describe what type (i.e. SONA extra credit, gift card, monetary). *If you are offering extra credit, please describe the non-research alternative way to earn the extra points. Please be sure to state this in the consent form along with a statement that students may stop participating at any time without losing the extra credit. To encourage participation, participants will be offered $20 cash as an honorarium at three intervals (total $60) : baseline, one-week post-intervention, six-month follow-up survey, and $50 for initial development of web mammogram focus group and post-intervention focus group.*

Section 3: Recruitment

18. How do you have access to the study population? In collaboration with the Community Advisory Board, participants will be recruited through flyers, newspapers, radio announcements, social service agencies, ethnic community organizations, colleges, and ethnic events. Flyers and announcements will describe the purpose of the project, eligibility criteria, and contact information. Interested AI women will call the telephone number provided, and recruitment staff will screen potential participants over the phone to determine whether they meet the inclusion criteria.

19. Are you obtaining subjects from private records (i.e. through your job, volunteer work, internship, etc.)? The data could be consider private records unless it is publicly available to anyone.
    - ☐ Yes: Describe how you have permissible access.
    - ☒ No

20. How will you initially contact and select the participants? (i.e. letter, e-mail, or advertisement). *You must include all recruitment, announcements, and invites with your IRB application. Make sure they include the word "research", your study purpose, estimated time commitment, eligibility criteria, and your contact information for questions* Participants will be recruited through flyers, newspapers, radio announcements, social service agencies, ethnic community organizations, colleges, and ethnic events. Flyers and announcements will describe the purpose of the project, eligibility criteria, and contact information. Interested AI women will call the telephone number provided, and recruitment staff will screen potential participants over the phone to determine whether they meet the inclusion criteria.

21. Describe how the subject's privacy will be protected? (I.e. testing or interviewing in private) *Privacy is about the person NOT the data…think about where the procedures will be conducted.* Participants will conduct a survey in a private conference.

22. Will there be a link to identify subjects? *This could be a name, code, or reference that might be used to identify the subject outside of the context of the research setting. The key question is, "Is there any way that anyone, including the investigator, could start with a data record and trace it back to the person being studied?" If yes, then there is an identifier linked to the subject.*
    - ☐ Yes: Explain the link and justify its use.

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☒ No – Skip to question 25 below

23. Who will have access to the identifiers and who will keep the link?

24. How will you limit access to the subject identifiers?

25. Describe the security plan for data including where it will be stored and how long, noting that you many not keep identifiable data indefinitely. All data obtained will be kept confidential in accordance with the provision of title 42 Code of Federal Regulations and HIPPA. All hard copy information will be kept in locked files, in locked rooms only accessible by Dr. Roh. All data collected during the study will be entered into an electronic data system by a unique ID code that will be assigned to each participant. Access to computer files will be only Dr. Roh. All data will be maintained in a computerized data system on a secured and firewall protected server. Hard copies of the focus group and interview transcripts, notes, and surveys will be kept in locked cabinets for 3 years in the USD Department of Social Work.

    Results from the study will be provided in the aggregate to avoid identification of any individual participant. Results will not be shared when there are not sufficient cases to assure confidentiality or when characteristics clearly identify a particular participant. No reports will include any identifying information on participants and no participant-specific information will be released without written permission of the participant.

26. Do you agree to keep a copy of the de-identified data for 3 years after the study closure?
    ☒ Yes
    ☐ No

Most exempt studies require a participant to be given a consent statement or a cover letter.

27. Check (✓) all that apply. Prepare and attach forms/scripts for review.
    ☐ Parental Consent (If the research is on a minor, parental consent is required. If minors are over 12 they can also sign the parental consent if it is written at a low literacy level.)
    ☒ Informed Consent (Adults)
    ☐ Assent Written (If child is ages 7-11 a written assent or verbal assent is required. Verbal assent requires a script.)
    ☐ Assent-written within parental consent
    ☐ Assent-verbal, script needed
    ☐ Consent Statement (This can only be used on adults when no identifiers are collected.)
    ☐ Cover Letter (This is similar to the consent statement but is in letter format.)

Templates can be found at http://www.usd.edu/research/irb-application-forms. Please utilize the templates to ensure regulatory compliance and avoid delays in processing this application.

28. If you will be using a consent statement or cover letter how will you obtain the consent?
    ☐ Mailed to the subject
    ☒ Verbal/Handout (face to face
    ☐ Web-based
    ☐ Verbal (telephone)

29. Describe what will be said to the participant to introduce the research. If your study is a telephone survey or interview, you must include a telephone script. You are invited to participate in a research study. The purpose of this study is to develop and evaluate the feasibility and effectiveness of the Mobile Web App Breast Cancer Screening (wMammogram) intervention that is culturally tailored for AI women. In order to participate, you must be 40 or older AI women. Taking part in this research project is voluntary. Please take time to read this flyer and ask questions before deciding whether to take part in this research project.

Section 4: Risks and Benefits

30. Are there any of the following risks associated with the research? Please check all that apply.
    ☐ Use of identifiable audio or video for data collection.
    ☐ Physical Risk
    ☐ Economic Risk
    ☐ Psychological Risk
    ☐ Legal Risk
    ☐ Social Risk

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☐ Use of private records including educational records or medical charts
☐ Collection of information that would be reportable to authorities or collection of information that might render the subject prosecutable under the law (e.g. child abuse, alcohol abuse, alcohol abuse by a pregnant woman, danger to self or others.)

31. If you checked any boxes above, describe the nature of each risk and how you've attempted to minimize it. These risks must be present in the consent form. Click here to enter text.
32. What direct and societal benefits do you expect the subject(s) you enroll to receive from this study? *If there is no direct benefit to the subjects, simply state that. There is no direct benefit to the subjects.*

33. Have you notified all areas (personnel and facilities) that need to be prepared to assist you in your research?
    ☒ N/A
    ☐ Yes – please list area and contact person's title.

HIPAA authorizations or waivers may be appropriate if you are collecting Protected Health Information (PHI) from a hospital, medical center, doctor's office etc.

34. Check PHI that you are collecting
    ☐ Names
    ☐ Email addresses
    ☐ Device identifiers
    ☐ Web universal resource
    ☐ Any unique identifying serial numbers
    ☐ Phone numbers; fax numbers,
    ☐ Medical Record numbers
    ☐ Full face photographic
    ☐ Social Security Numbers
    ☐ Geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code
    ☐ Elements of dates related to the individual, i.e. birthdate, admission date, discharge date, death.
    ☐ Health plan beneficiary numbers; account numbers; certificate/license numbers
    ☐ Vehicle identifiers and serial numbers, including license plate numbers

35. Does your study require HIPAA authorization or Waivers?
    ☒ N/A
    ☐ Full Waiver http://www.usd.edu/research/irb-general-forms
    ☐ Partial Waiver http://www.usd.edu/research/irb-general-forms
    ☐ Authorization Addendum (A study-specific Research Subject HIPAA Authorization (stand-alone) form must be attached)

Signature Page

You must send a copy of this section to the IRB office to complete your application. You may submit it as a PDF, or send it to the University of South Dakota, Office of Human Subjects Protection, 414 E. Clark, Slagle Hall 107, Vermillion, SD 57069.

Title of Study: Intervention to Promote Breast Cancer Screening Among American Indian Women
Investigator(s) Name: **Soonhee Roh, PhD**

By signing below, I attest that the information provided in this form is correct. I agree to seek and obtain prior written approval from the IRB for any substantive modifications in the proposal, including changes in procedure, co-investigators, consent statements, survey/interview questions, etc. I will immediately report any unexpected or unanticipated problems or incidents that occur during the study. I will report in writing any significant findings which develop during the course of the study which may affect the risks and benefits to the participants. I will not begin my research until I have received approval from the IRB. I will abide by the IRB requests for to report on the status of the study. I will maintain the records and documents of this research. If there is a grant associated with this research, it completely reflects what is contained in this application. If the above conditions are not met, I understand that approval of this research could be suspended or terminated.

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SOUTH DAKOTA

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Protocol Number

Principal Investigator Signature: Soonhee Roh 08/7/2019
Date

Student Investigator Signature: _____
Date

Honors Director and Department Chair or Dean Assurances:

By signing below, I attest that I reviewed the above application and find the research is scientifically and scholarly sound and that competencies and resources are adequate.

Honors Director Signature: _____
Signature Date

By signing below, I attest that I reviewed the above application and find the research is scientifically and scholarly sound and that competencies and resources are adequate.

Department Chair or Dean Signature:

Frank Zavodil August 8, 2019,
Signature Date

Submission Type: Modification Date: 2-4-2025

IRB #: 2019-053
Title: Exped-Intervention to Promote Breast Cancer Screening Among American Indian Women
Creation Date: 7-1-2021
Status: Review Complete
Principal Investigator: Soon Hee Roh

Project Update/Amendment Form

Select how your initial submission was made:

- Cayuse
- ✓ Paper form or A-Tune

Legacy Data: Amendment Form

*required

1. **What are you revising?**

- [x] Consent Form
- [ ] Advertisements
- [ ] Questionnaire/Survey
- [ ] Adding a site or location
- [ ] Investigator Brochure
- [ ] Letter(s) of permission
- [ ] IRB approvals other than USD IRB
- [ ] Administrative letter
- [ ] Closed to accrual
- [ ] Other

2. **Change of Personnel:**

- [ ] Add Personnel
- [ ] Remove Personnel

*required

3. **Is the change significant?**

Yes

✓ No

*required

4. **Please describe the change.**

I made separate informed consent form both control and experimental group.

*required

5. **What is the reason for the change?**

For more effective intervention

*required

6. **How would the proposed revision change the level of risk to the subjects?**

Increase

Decrease

✓ No change

*required

7. **Will this have an impact on the study and/or participants?**

Yes

✓ No

*required

8. **Are there changes needed to the consent form?**

✓ Yes

Attach a copy of the revised consent with the changes tracked or underlined and a clean copy for the IRB date-stamp at the bottom.

Do you have subjects enrolled with the previous consent?

Yes

✓ No

No

9. **Attach all modified/updated documents:**

✓ Informed Consent

Telephone scripts

Protocols from sponsors

Investigator brochure

Advertisements, flyers, posters

Surveys, questionnaires, interview questions

updated and original IRB application

CITI certificates

Final-0527-2021-Experimental Group Informed consent form.doc

Roh_Consent_Control Group by SHR-052621-Submit to JS.doc

Legacy Form

*required

Principal Investigator

Name: Soon Hee Roh
Organization: Social Work
Address: 1400 W 22nd Street SF HSC, Sioux Falls, SD 57105-1570
Phone: 605-357-1450
Email: soonhee.roh@usd.edu

*required

Primary Contact

Name: Serene Thin Elk
Organization: Psychiatry
Address: , Vermillion, SD 57069-2390
Phone:
Email: serene.thinelk@gmail.com

Co-Investigator(s)

Name: Yeon-Shim Lee
Organization: External IRB Study
Address: , Vermillion, SD 57069-2390
Phone:
Email: YL375@sfsu.edu

Name: Shasheen Thin Elk
Organization: External IRB Study
Address: , Vermillion, SD 57069-2390
Phone:
Email: SthinElk@yanktonsiouxtribe.net

Student Investigator(s)

Name: Johanna Tietze
Organization: IRB Student Users
Address: , Vermillion, SD 57069-2390
Phone:
Email: Johanna.Tietze@coyotes.usd.edu

Study Documents

2019.053-RohLee_InterventiontoPromote...AmericanIndianWomen.pdf

Submission Type: Modification Date: 2-4-2025

IRB #: 2019-053
Title: Exped-Intervention to Promote Breast Cancer Screening Among American Indian Women
Creation Date: 10-1-2021
Status: Review Complete
Principal Investigator: Soon Hee Roh

Project Update/Amendment Form

Select how your initial submission was made:

Cayuse

✓ Paper form or A-Tune

Legacy Data: Amendment Form

*required

1. **What are you revising?**

- ✓ Consent Form
- ✓ Advertisements
- ✓ Questionnaire/Survey
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- Investigator Brochure
- Letter(s) of permission
- IRB approvals other than USD IRB
- Administrative letter
- Closed to accrual
- Other

2. **Change of Personnel:**

- Add Personnel
- Remove Personnel

*required

3. **Is the change significant?**

Yes

✓ No

*required

Please describe the change.

4.
- There were minor grammatical changes made the consent statements and pre-test. There were also changes to the participant payment information and include both informed consent forms and the updated flyers. Additionally, we changed our post-test based on our usability test and community advisory board members' suggestions and added sections VIII and IX and have a safety plan listed in the consent statements. We added an additional language as follow "If you may 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)". This information will be included in the informed consent form.

*required

What is the reason for the change?

5.
- Based on input and suggestions from our usability test and community advisory board members, we included additional questions that have been associated with cancer care and health behaviors.

*required

6. **How would the proposed revision change the level of risk to the subjects?**

Increase

Decrease

✓ No change

*required

7. **Will this have an impact on the study and/or participants?**

Yes

✓ No

*required

8. **Are there changes needed to the consent form?**

✓ Yes

Attach a copy of the revised consent with the changes tracked or underlined and a clean copy for the IRB date-stamp at the bottom.

Do you have subjects enrolled with the previous consent?

Yes

✓ No

No

9. **Attach all modified/updated documents:**

✓ Informed Consent

Telephone scripts

Protocols from sponsors

Investigator brochure

✓ Advertisements, flyers, posters

✓ Surveys, questionnaires, interview questions

updated and original IRB application

CITI certificates

2021---wMammogram flyer-submit -100121 for stamp .doc

Control Group Informed Consent Form-Clean version for stamp-100121.doc

Control Group Informed Consent Form-track change version-100121.doc

Control-Brochure-FINAL-9-30-21.pdf

Experiment GP-Informed Consent Form-Clean version for stamp-100121.doc

Experiment GP-Informed Consent Form-Track change version-100121.doc

Post-test Control Group-100121.doc

post-test-mobile web app -Experiment GP-100121.doc

Pre-test-all participants-100121.doc

USD IRB Amendment Application-100121.docx

Legacy Form

*required

Principal Investigator

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Student Investigator(s)

Name: Johanna Tietze
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Study Documents

2019.053-RohLee_InterventiontoPromote...AmericanIndianWomen.pdf

Submission Type: Modification Date: 2-4-2025

IRB #: 2019-053
Title: Exped-Intervention to Promote Breast Cancer Screening Among American Indian Women
Creation Date: 5-2-2022
Status: Review Complete
Principal Investigator: Soon Hee Roh

Project Update/Amendment Form

Select how your initial submission was made:

Cayuse

✓ Paper form or A-Tune

Legacy Data: Amendment Form

*required

1. **What are you revising?**

- [ ] Consent Form
- [x] Advertisements
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- [ ] IRB approvals other than USD IRB
- [ ] Administrative letter
- [ ] Closed to accrual
- [ ] Other

2. **Change of Personnel:**

- [ ] Add Personnel
- [ ] Remove Personnel

*required

3. **Is the change significant?**

Yes

✓ No

*required

4. **Please describe the change.**

We have 2 days of focus group meetings instead of one day meeting.

*required

5. **What is the reason for the change?**

Prospective focus group members request more time slots for their attendance.

*required

6. **How would the proposed revision change the level of risk to the subjects?**

Increase

Decrease

✓ No change

*required

7. **Will this have an impact on the study and/or participants?**

Yes

✓ No

*required

8. **Are there changes needed to the consent form?**

Yes

✓ No

9. **Attach all modified/updated documents:**

Include the track changes version and a clean version in word format.

Informed Consent

Telephone scripts

Protocols from sponsors

Investigator brochure

✓ Advertisements, flyers, posters

Surveys, questionnaires, interview questions

updated and original IRB application

CITI certificates

Final-Follow-up focus group flyer-042722-request to Announcer.doc

Final-Follow-up focus group flyer-042722-request to Announcer.pdf

Attach other approved documents associated with this modification.

10.

(Only attach current approved versions)

Legacy Form

*required

Principal Investigator

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Submission Type: Modification Date: 2-4-2025

IRB #: 2019-053
Title: Exped-Intervention to Promote Breast Cancer Screening Among American Indian Women
Creation Date: 7-1-2021
Status: Review Complete
Principal Investigator: Soon Hee Roh

Project Update/Amendment Form

Select how your initial submission was made:

- Cayuse
- ✓ Paper form or A-Tune

Legacy Data: Amendment Form

*required

1. **What are you revising?**

- [x] Consent Form
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- [ ] Administrative letter
- [ ] Closed to accrual
- [ ] Other

2. **Change of Personnel:**

- [ ] Add Personnel
- [ ] Remove Personnel

*required

3. **Is the change significant?**

Yes

✓ No

*required

4. **Please describe the change.**

I made separate informed consent form both control and experimental group.

*required

5. **What is the reason for the change?**

For more effective intervention

*required

6. **How would the proposed revision change the level of risk to the subjects?**

Increase

Decrease

✓ No change

*required

7. **Will this have an impact on the study and/or participants?**

Yes

✓ No

*required

8. **Are there changes needed to the consent form?**

✓ Yes

Attach a copy of the revised consent with the changes tracked or underlined and a clean copy for the IRB date-stamp at the bottom.

Do you have subjects enrolled with the previous consent?

Yes

✓ No

No

9. **Attach all modified/updated documents:**

✓ Informed Consent

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Investigator brochure

Advertisements, flyers, posters

Surveys, questionnaires, interview questions

updated and original IRB application

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Roh_Consent_Control Group by SHR-052621-Submit to JS.doc

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Organization: External IRB Study
Address: , Vermillion, SD 57069-2390
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Student Investigator(s)

Name: Johanna Tietze
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Study Documents

2019.053-RohLee_InterventiontoPromote...AmericanIndianWomen.pdf

Submission Type: Modification Date: 2-4-2025

IRB #: 2019-053
Title: Exped-Intervention to Promote Breast Cancer Screening Among American Indian Women
Creation Date: 10-1-2021
Status: Review Complete
Principal Investigator: Soon Hee Roh

Project Update/Amendment Form

Select how your initial submission was made:

Cayuse

✓ Paper form or A-Tune

Legacy Data: Amendment Form

*required

1. **What are you revising?**

- ✓ Consent Form
- ✓ Advertisements
- ✓ Questionnaire/Survey
- Adding a site or location
- Investigator Brochure
- Letter(s) of permission
- IRB approvals other than USD IRB
- Administrative letter
- Closed to accrual
- Other

2. **Change of Personnel:**

- Add Personnel
- Remove Personnel

*required

3. **Is the change significant?**

Yes

✓ No

*required

Please describe the change.

4.
- There were minor grammatical changes made the consent statements and pre-test. There were also changes to the participant payment information and include both informed consent forms and the updated flyers. Additionally, we changed our post-test based on our usability test and community advisory board members' suggestions and added sections VIII and IX and have a safety plan listed in the consent statements. We added an additional language as follow "If you may 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)". This information will be included in the informed consent form.

*required

What is the reason for the change?

5.
- Based on input and suggestions from our usability test and community advisory board members, we included additional questions that have been associated with cancer care and health behaviors.

*required

6. **How would the proposed revision change the level of risk to the subjects?**

Increase

Decrease

✓ No change

*required

7. **Will this have an impact on the study and/or participants?**

Yes

✓ No

*required

8. **Are there changes needed to the consent form?**

✓ Yes

Attach a copy of the revised consent with the changes tracked or underlined and a clean copy for the IRB date-stamp at the bottom.

Do you have subjects enrolled with the previous consent?

Yes

✓ No

No

9. **Attach all modified/updated documents:**

✓ Informed Consent

Telephone scripts

Protocols from sponsors

Investigator brochure

✓ Advertisements, flyers, posters

✓ Surveys, questionnaires, interview questions

updated and original IRB application

CITI certificates

2021---wMammogram flyer-submit -100121 for stamp .doc

Control Group Informed Consent Form-Clean version for stamp-100121.doc

Control Group Informed Consent Form-track change version-100121.doc

Control-Brochure-FINAL-9-30-21.pdf

Experiment GP-Informed Consent Form-Clean version for stamp-100121.doc

Experiment GP-Informed Consent Form-Track change version-100121.doc

Post-test Control Group-100121.doc

post-test-mobile web app -Experiment GP-100121.doc

Pre-test-all participants-100121.doc

USD IRB Amendment Application-100121.docx

Legacy Form

*required

Principal Investigator

Name: Soon Hee Roh
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*required

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2019.053-RohLee_InterventiontoPromote...AmericanIndianWomen.pdf

Submission Type: Modification Date: 2-4-2025

IRB #: 2019-053
Title: Exped-Intervention to Promote Breast Cancer Screening Among American Indian Women
Creation Date: 5-2-2022
Status: Review Complete
Principal Investigator: Soon Hee Roh

Project Update/Amendment Form

Select how your initial submission was made:

Cayuse

✓ Paper form or A-Tune

Legacy Data: Amendment Form

*required

1. **What are you revising?**

- [ ] Consent Form
- [x] Advertisements
- [ ] Questionnaire/Survey
- [ ] Adding a site or location
- [ ] Investigator Brochure
- [ ] Letter(s) of permission
- [ ] IRB approvals other than USD IRB
- [ ] Administrative letter
- [ ] Closed to accrual
- [ ] Other

2. **Change of Personnel:**

- [ ] Add Personnel
- [ ] Remove Personnel

*required

3. **Is the change significant?**

Yes

✓ No

*required

4. **Please describe the change.**

We have 2 days of focus group meetings instead of one day meeting.

*required

5. **What is the reason for the change?**

Prospective focus group members request more time slots for their attendance.

*required

6. **How would the proposed revision change the level of risk to the subjects?**

Increase

Decrease

✓ No change

*required

7. **Will this have an impact on the study and/or participants?**

Yes

✓ No

*required

8. **Are there changes needed to the consent form?**

Yes

✓ No

9. **Attach all modified/updated documents:**

Include the track changes version and a clean version in word format.

Informed Consent

Telephone scripts

Protocols from sponsors

Investigator brochure

✓ Advertisements, flyers, posters

Surveys, questionnaires, interview questions

updated and original IRB application

CITI certificates

Final-Follow-up focus group flyer-042722-request to Announcer.doc

Final-Follow-up focus group flyer-042722-request to Announcer.pdf

Attach other approved documents associated with this modification.

10.

(Only attach current approved versions)

Legacy Form

*required

Principal Investigator

Name: Soon Hee Roh
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