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ENHANCING CANCER PREVENTION AND CONTROL PATHWAYS IN THE ZUNI PUEBLO – NATIVE HEALTH INITIATIVE

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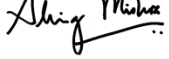
Principal Investigator(s) Approval/Signature Page

The signature below constitutes the approval of this protocol and all attachments as necessary. It provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable U.S. federal regulations and ICH guidelines.

All formal protocol amendments will be approved by the study Principal Investigator(s) as indicated by provision of new Signature Pages and associated dates. This includes all changes to study PIs.

Document Version Number and Date: V23 (October 30, 2023)

(Replace this page for each study *amendment* to the final version 1.0)

Role	**(Please type name)**	**Signature**	**Date**
Principal Investigator:	Shiraz I. Mishra		October 30, 2023

PROTOCOL TITLE:

Enhancing Cancer Prevention and Control Pathways in the Zuni Pueblo – Native Health Initiative

PRINCIPAL INVESTIGATOR:

Shiraz I. Mishra
Department of Pediatrics

VERSION NUMBER:

V23

DATE:

October 30, 2023

REGULATORY FRAMEWORK:

Please indicate all that apply:

☐	DOD (Department of Defense)
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Is this a clinical trial under ICH-GCP E6? ☐ Yes ☒ No

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http://www.fda.gov/downloads/Drugs/Guidances/ucm073122.pdf

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1. Objectives

There are continued disparities in cancer incidence, mortality, and survival between American Indians (AIs) and Whites on cancers responsive to early screening (i.e., breast, colon-rectum [CR], and cervical) in the US. In New Mexico (NM), AIs compared with other racial/ethnic populations are significantly less likely to adhere to recommended screening guidelines. Differences in screening rates between AIs and Whites in NM range from a low of 11.5% (breast) to a high of 27.3% (CR)[1-4]. There is an urgent need for testing culturally and linguistically targeted and theoretically guided interventions that support AIs in meeting the Healthy People 2020 targets for screen detectable cancers (breast: 81.1%; CR: 70.5%; cervix: 93.0%). Our long-term goal is to enhance heath equity and reduce cancer disparities in morbidity, mortality, stage-at diagnosis, and survival among Zuni people through effective screening and prevention interventions. Our overall objective, which is the next step toward attainment of our long-term goal, is to develop a new participatory collaboration for cancer control research with the largest tribal community in NM (Zuni Pueblo) and the Indian Health Service (IHS) Zuni Comprehensive Health Center to conjointly build research capacity, assess cancer control needs of the Zuni people, identify strategies to enhance screening for the three screen detectable cancer (breast, CR, and cervix) per recommended guidelines, define cancer prevention and control priorities, develop a Zuni-specific cancer research plan and a model for cancer research among other AI tribes in rural NM, and develop and pilot test culturally and linguistically appropriate interventions to enhance age- and risk-appropriate breast, CR, and cervical cancer screening in concordance with the U.S. Preventive Services Task Force recommended guidelines. This research project is designed to use a formative, mixed-method approach to answer the research questions: "What are the cancer control needs and community-identified intervention strategies to control and prevent the three screen detectable cancers among the Zuni people"? And, "Does multi-directional and participatory cancer-related training, education, and cancer prevention and control intervention research enhance cancer health equity among the Zuni people?" The rationale for this study is that once we know the cancer control needs of the Zuni people and their preferences for the design of intervention programs for the three cancers, we can develop, implement and test the efficacy of targeted evidence based and theoretically informed cancer control and prevention interventions. [NOTE: At the request of the Zuni tribal leaders, we have included prostate cancer in the proposed formative research as the leaders would like to learn about their communities' views regarding prostate cancer. There are no Community Guide recommendations or Health People 2020 targets for screening for prostate cancer.]

We plan to test our central hypothesis and, thereby, accomplish the overall objective by pursuing the following specific aims:

Aim 1: Develop a sustainable multi-directional, participatory collaboration ("community collaborative") between the Zuni tribal leadership, Zuni stakeholders (i.e., Health and Wellness program directors and Community Health Representatives [CHRs], cancer survivors), IHS Zuni Comprehensive Health Center, Albuquerque Area Southwest Tribal Epidemiology Center (AASTEC), and the UNM Comprehensive Cancer Center (UNM CCC). We will establish a Tribal Advisory Panel (TAP) and community collaborative with representation from entities list here.

Aim 2: Empower and develop capacity (using the Freirean educational pedagogy for adult learning) among Zuni people to participate in relevant cancer control education and research.

- **Aim 2a:** Train Zuni Community Health Representatives (CHRs) in qualitative research.
- **Aim 2b:** Educate CHRs about cancers of the breast, CR, cervix, and prostate.

Aim 3: Assess cancer control needs of the Zuni people for the screen detectable cancers and prostate cancer, and resources available at the Indian Health Service (IHS) Zuni Comprehensive Health Center to provide screening services.

Aim 3a: Elicit and document (using the Multi-level Health Outcomes Framework [MHOF]) for cancers of the breast, CR, cervix, and prostate prevailing knowledge and beliefs; prevention an early detection practices; facilitators and barriers to risk reduction and screening practices; facilitators and barriers to accessing screening services; and, potential strategies/interventions to enhance cancer screening. We postulate that the qualitative methods will provide contextually rich data on what the Zuni people know about the screen detectable cancers and prostate cancer, what their beliefs are about these cancers, how their beliefs and cultural norms influence help-seeking behaviors, and what multi-level and multi-component strategies must we implement to enhance screening.

Aim 3b: Document resources available at the IHS Zuni Comprehensive Health Center. We postulate that the IHS Zuni Comprehensive Health Center will be under-resourced to provide screening services.

Aim 4: Evaluate the cancer-related knowledge, attitudes, and self-reported cancer-screening practices using quantitative survey methods among a convenience sample of Zuni people. We postulate that the survey will validate the information collected through the focus groups.

Aim 5: Integrate data to better understand cancer prevention and control challenges for the Zuni people:

(a) Ascertain cancer burden, risk factors, and screening rates among the Zuni people.
(b) Synthesize data collected as part of Aim 3b on resources available in the community, IHS Zuni Comprehensive Health Center, and at UNM CCC that can address the Advisory Panel-identified cancer prevention and control priorities.
(c) Synthesize data collected as part of the qualitative and quantitative research (Aims 3a and 4).

Aim 6: Develop a cancer prevention and control research agenda for tribal communities in rural NM:

(a) Develop a Zuni-specific comprehensive plan for research and evidence-based interventions in cancer prevention and control.
(b) Design a model, based on the lessons learned, for a collaborative cancer prevention and control research agenda for tribal communities across rural NM.

Aim 7: Using participatory approaches by engaging the TAP, finalize multilevel/multicomponent intervention strategies to increase provider delivery of, community access to, and community demand for screening for the screen-detectable cancers.

Aim 8: Pilot test (using quantitative and qualitative methods) the multilevel/ multicomponent culturally and linguistically appropriate intervention strategies on outcomes such as: impact on screening practices; feasibility of implementation and acceptability of the intervention; and cost effectiveness of the intervention.

2. Background

Cancer epidemiology and screening rates. There are continued disparities in cancer incidence, mortality, and survival between AIs and Whites on cancers responsive to early screening (i.e., breast, colon-rectum [CR], and cervical) and prostate cancer in the United States (U.S.). For the period 1990-2009, based on data from Contract Health Service Delivery Area Counties across the U.S., the mortality-to-incidence ratios (indicator of survival) for these cancers were significantly higher for American Indian/Alaska Natives compared to Whites (breast: 1.22, CR: 1.16, cervix: 1.36, prostate: 1.40)[5], indicating poorer survival. AIs in New Mexico also experience substantial cancer health disparities. For the period 2010-2014, AIs compared to Whites had higher incidence rates (per 100,000) for cervical (7.9 vs. 6.9) and CR (male: 46.5 vs. 35.2; female: 29.2 vs. 28.2) cancers, and higher mortality rates for cervical (3.7 vs. 1.3) and CR (males only; 18.9 vs. 15.6) cancers[6]. AIs were also more likely to receive a late-stage (i.e., regional or distant)

cancer diagnosis for all three screen detectable cancers[7]. AIs have some of the lowest cancer screening rates compared with other racial/ethnic groups. In New Mexico, AIs listed in the IHS Albuquerque Area have substantially lower screening rates than the state's White population do. AIs had screening rates of: breast (58.5%, women ages 52-64), CR (41.9%, ages 50-75), and cervical (63.9%, women ages 24-64) cancers[1]; whereas, screening rates for Whites were: breast (70.0%, ages 50-74)[4], CR (69.2%, ages 50-75)[2], and cervical (77.8%, women 21-65)[3].

Barriers to screening. AIs experience substantial barriers when accessing and utilizing cancer-screening services. They hold varying cancer-related belief systems that influence the modalities of health care they seek. Tribes possess remarkably few health care resources to address cancer disparities where health care is significantly underfunded, services are often fragmented, and acute care needs take precedence over preventive health services[8]. Many IHS facilities have insufficient staff and high provider turnover, which results in abbreviated patient-provider encounters and insufficient communication[8]. Other documented barriers to cancer screening among AIs include cost/insurance, fear, stigma, transportation, embarrassment, trust, perceptions of discrimination, privacy issues, beliefs, knowledge about cancer screening, limited access to healthcare providers, lack of symptoms, and no screening recommendation made by providers[9-18].

Summary of Significance. AIs experience substantial disparities in screen detectable cancer with higher incidence, disproportionate diagnosis of late stage disease, higher mortality, and poorer survival. Despite the documented efficacy of screening exams when used per recommended guidelines, AIs have lower screening rates; in part attributable to individual, social, and structural barriers. There is a paucity of data specific to Zuni people on their knowledge, attitudes, beliefs regarding cancer and cancer screening, and about potential strategies to enhance cancer screening. Therefore, the first necessary step is to document Zuni people's needs regarding screen detectable cancers. Future studies will utilize the results from this project to inform the development, implementation, and efficacy testing of intervention strategies that are tailored to the unique cancer control needs of the Zuni people and target the Zuni community.

Innovation

The proposed research is innovative, in our opinion, for the following reasons. First, it uses participatory research approaches[19,20] to develop a "community collaborative" and to train Zuni CHRs for cancer control research and education. Second, it documents barriers and seeks solutions from Zuni community members towards the design of specifically tailored and targeted cancer prevention and control interventions, as recommended[21-24]. Third, it uses a multi-level theory of behavior change[25-27] to analyze formative data, along individual, environmental, contextual, social, and policy promoters and barriers[28] for behavior change. Fourth, it works collaboratively with a population that experiences acute health inequities to determine needs and intervention strategies. Fifth, it uses multiple methods (qualitative and quantitative, including constituency-involving processes) for data collection. These innovative steps will provide for the translation and implementation of more meaningful and realistic cancer prevention and control interventions that are applicable to "real world" settings by being responsive to community needs while acknowledging limitations of treatment-focused healthcare services, challenges to local healthcare access, and the exigencies of limited healthcare resources.

3. Study Design

Preliminary Work. Dr. Mishra has conducted community-engaged descriptive and evaluative health disparities research using mixed methods (including quantitative surveys, and qualitative focus groups and semi-structured interviews) with a special emphasis on breast, CR, and cervical cancer screening[22,23,29-31].

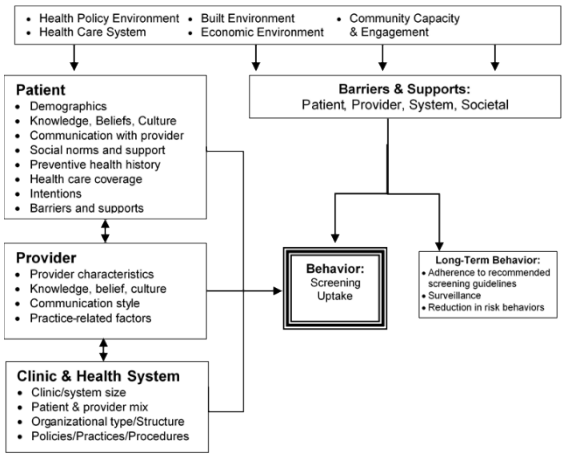
General Overview. We will conduct the study in the Zuni Pueblo, in community-based settings and in the IHS Zuni Comprehensive Health Center. We will develop capacity among Zuni CHRs for cancer education

and research (Aim 1). Next, we will use a qualitative design featuring focus groups with community members and focus groups or interviews with healthcare providers (Aim 2). This formative work will enable us to learn about the range of factors that influence cancer screening and potential strategies to enhance it. Lastly, we will validate the qualitative findings using a quantitative design featuring a population-based survey of community members (Aim 3).

Research Setting. The Pueblo of Zuni is the largest tribal community in NM. The main Zuni reservation is located in McKinley and Cibola counties in the western part of NM. Based on the non-metropolitan 2013 Rural-Urban Continuum Codes (RUCC), these counties are in category 5. The Zuni Pueblo is a small rural community (~11000 residents), 97% of whom are American Indian[32]. Nearly 90% of the residents of Zuni speak a language other than English (i.e. the Zuni language-"Ashiwi awan benawe") at home[32]. The population is relatively young (median age, 33.2 years) and 72.4% are high school graduates or higher. More than one-third (37.5%) live below the poverty level, with a median household income of about $38,000[32].

Theoretical Framework. The Multi-level Health Outcomes Framework (MHOF) is a conceptual model to guide descriptive and intervention research in cancer prevention and control[25-27]. The MHOF is a synthesis of several conceptual formulations in the area of health behavior and outcomes and takes a multi-level (socio-ecological) perspective. The MHOF is a critical asset as it provides a framework for systematically analyzing the descriptive data collected for the proposed study. The MHOF has been applied and tested in a wide range of studies involving multiple racial and ethnic groups, disease targets, and intervention types and has been shown to be robust[22,26,27].

Figure: Multi-level Health Outcomes Framework



Community-Based Participatory Research (CBPR). This approach effectively addresses mistrust of research and researchers through establishing a non-hierarchical partnership model[19,20]. CBPR is used successfully to address a variety of health priorities[19,20] and is a necessary research methodology with AIs[33-36]. We will constitute an Advisory Panel comprising stakeholders representing Zuni community members and CHRs, cancer survivors, IHS healthcare providers, and researchers. The Panel will actively participate in the research, including finalization of the study aims, research design and approach, recruitment strategies, development of data collection instruments, and constituency checking of data inferences. We will (1) build on the various stakeholders' strengths, and integrate our respective knowledge and expertise and (2) support an inter-dependent partnership, with a long-term commitment for mutually beneficial co-learning and capacity enhancement. The Panel will comprise nine members and will meet every six months or more often if necessitated. Panel members will receive $100 for their participation and contributions.

4. Inclusion and Exclusion Criteria

4.1. People will be screened for eligibility for the respective sub-projects (Aims 3, 4, 7, and 8) by trained staff. Participants who meet the inclusion criteria for the sub-projects, as defined below according to self-report on the screening form, will be invited to participate in the respective part of the study.

4.2. **Inclusion Criteria for Aim 3 – AI Female Aged 50-75 Year Focus Groups**

4.2.1. *Criteria for Focus Groups on Cancers of the Breast, Colon-Rectum, and Cervix*:

4.2.1.1. AI woman aged 50-75 years old

4.3. Inclusion Criteria for Aim 3 – AI Male Aged 50-75 Year Focus Groups

4.3.1. *Criteria for Focus Groups on Cancers of the Colon-Rectum and Prostate*:

4.3.1.1. AI man aged 50-75 years old

4.4. Inclusion Criteria for Aim 3 – AI Female Aged 21-49 Year Focus Groups

4.4.1. *Criteria for Focus Groups on Cancer of the Cervix*:

4.4.1.1. AI woman aged 21-49 years old

4.5. Inclusion Criteria for Aim 3 – Tribal Advisory Panel (TAP) member Focus Group

4.5.1. Member of the Tribal Advisory Panel

4.6. Inclusion Criteria for Aim 3 – Healthcare Provider Focus Group

4.6.1. Provide healthcare within the IHS Zuni Comprehensive Health Center

4.7. Inclusion Criteria for Aim 4 – AI Male and Female Surveys (see "EligibilityScreener_Survey_2020_06_22_V1")

4.7.1. *Cervical Cancer Survey*: AI women 21-49 years old and residing in the Zuni Pueblo

4.7.2. *Colorectal, Breast, and Cervical Cancer Survey*: AI women 50-75 years old and residing in the Zuni Pueblo

4.7.3. *Colorectal and Prostate Cancer Survey*: AI men 50-75 years old and residing in the Zuni Pueblo

4.8. Inclusion Criteria for Aim 7 – Development of the Interventions (Focus Groups to Develop Small Media)

4.8.1. AI man aged 50-75 years old

4.8.2. AI woman aged 21-75 years old

4.9. Inclusion Criteria for Aim 8 – Pilot Testing of the Interventions

4.9.1. For the Breast Cancer Intervention: AI women age 50-75, average risk for breast cancer, and never had a mammogram OR not had a mammogram within the past 2 years.

4.9.2. For the Colorectal Cancer Intervention: AI men and women aged 45-75, average risk for CR cancer, and never had a fecal occult blood test (FOBT), or fecal immunochemical test (FIT) or a colonoscopy OR not had a FOBT or FIT in the past year, OR no colonoscopy in the past 10 years.

4.9.3. For the Cervical Cancer Intervention: women aged 21-75, never had a cytology (Pap smear) OR had a Pap smear more than 3 years ago OR women aged 30-75, and never had screening with a combination of cytology and human papillomavirus testing OR no combination of testing in the past 5 years.

4.10. **Exclusion Criteria**

4.10.1. Cognitively impaired adults are excluded from participation
4.10.2. Adults not able to consent for themselves are excluded from participation
4.10.3. Prisoners may not participate in this study

5. Number of Subjects

5.1. Aim 3

5.1.1. Aim 3 is formative and therefore the sample size is not guided by a power analysis. For each of the up to 21 focus groups (until we reach thematic saturation), N=12-15 eligible persons will be invited, with the expectation that on average N=8-12 will attend. Since this is a community-based participatory study, we will not turn away any eligible person who show up for the focus group. Thus, we seek approval for including 150 AI men and women for the focus group.

5.1.1.1. *Focus Groups Among Women aged 50-75 on Cancers of Breast, Colon-Rectum, and Cervix:* up to 5 Focus Groups, or until we reach thematic saturation (participants: N=60-75)

5.1.1.2. *Focus Groups Among Men aged 50-75 on Cancers of the Colon-Rectum and Prostate:* up to 5 Focus Groups, or until we reach thematic saturation (participants: N=60-75)

5.1.1.3. *Focus Groups Among Women aged 21-49 on Cervical Cancer:* up to 5 Focus Groups, or until we reach thematic saturation (participants: N=60-75)

5.1.1.4. *Focus groups with Tribal Advisory Panel (TAP) members:* up to 3 Focus Groups, or until we reach thematic saturation (participants: N=36-45- total)

5.1.1.5. *Healthcare Provider focus groups:* up to 3 Focus Groups, or until we reach thematic saturation (participants: N=36-45 total)

5.2. Aim 4

5.2.1. Aim 4 is to conduct surveys with approximately N=250-280 eligible AI men and women.

5.2.1.1. *Survey on Cancer of the Cervix (Women aged 21-49)*: N=50-60 AI women

5.2.1.2. *Survey on Cancers of the Colon-Rectum, Breast, and Cervix (Women aged 50-75)*: N=100-110 AI women

5.2.1.3. *Survey on Cancers of the Colon-Rectum and Prostate (Men aged 50-75)*: N=100-110 AI men

5.3. Aim 7

5.3.1. Aim 7 is to develop the interventions, including the small media, with about 12-15 TAP members (section 4.5) and 150 eligible AI men and women (we will invite 12-15 participants

in up to 15 total focus groups, with expectation that on average we will have 8-10 participants will attend) (section 4.8)

5.4. Aim 8

5.4.1. Aim 8 is to test the three interventions with about up to 150 eligible participants

Total between the Aims: N=706-850 participants

6. Study Timelines

6.1. Aim 3 – Anticipated to occur over Year 1 of the study

6.1.1. Focus Groups: Participants will complete focus group activities anticipated to take about 2 hours for women and men aged 50-75, and about 60 minutes for women aged 21-49.

6.1.2. Focus Groups: Focus group activities with providers and Tribal Advisory Panel members anticipated to take about 45-60 minutes.

6.2. Aim 4 – Anticipated to occur over Year 2 of the study

6.2.1. Surveys: Participants will complete surveys anticipated to take up to 20 minutes for Men 50-75 years and Women 21-49 years, and 40 minutes for Women 50-75 years.

6.3. Aim 7 – Anticipated to occur over Year 3 of the study

6.3.1. Group discussion with TAP members 60 minutes

6.3.2. Focus Groups: Participants will complete focus group activities anticipated to take about 2 hours for women and men aged 50-75, and about 60 minutes for women aged 21-49.

6.4. Aim 8 – Anticipated to occur over Year 4-7 of the study

6.4.1. Baseline and 12 months post-intervention surveys: approximately 20-30 minutes each

6.4.2. Focus Groups or interviews: Participants will complete focus group activities anticipated to take up to 2 hours.

7. Study Endpoints

Endpoints for this study include completion of the 12-month post-intervention survey questionnaire by all eligible participants.

8. Research Setting

8.1. Patient Participant Recruitment

8.1.1. Participants will be recruited within the Zuni Pueblo community, working in community-based settings and with the IHS Zuni Comprehensive Health Center.

8.1.2. Dr. Mishra and his study team staff will work closely with each of these participating groups towards recruitment of eligible participants. The research team will coordinate these activities with Dr. English and the CHRs. The behavioral study coordinator will communicate on a weekly basis with CHRs for purposive recruitment to the focus groups and interviews in Aims 3 and 7, and convenience sampling recruitment to the surveys in pilot testing of the interventions in Aim 8. A waiver of written consent will be requested for all participants.

8.1.3. Participants for the focus groups in Aims 3 and 7, and pilot testing of the intervention will be recruited through community-based settings in Zuni. We will use a combination of community meetings, health fairs, announcements and flyers placed in public places such as the Tribal Administration building, Zuni Health Initiative center, Community Center, Post Office, IHS Zuni Comprehensive Health Center. Tribal leaders will identify Tribal Advisory Panel members or consent to those nominated by peers based on experience and expertise. Participants for Aim 4 (survey) will be recruited by placing/ distributing flyers (see "RecruitmentFlyer_Survey_2020_09_02_V2") to households selected from randomly identified streets in the Zuni Pueblo.

8.2. Provider Participant Recruitment

8.2.1. Provider participants for Aim 3 will be purposively recruited based on eligibility as a healthcare provider at the IHS Zuni Comprehensive Health Center.

8.3. Data Collection

8.3.1. The focus group sessions (Aims 3, 7, and 8) will be held at the Zuni Health Initiative's center. The focus group with healthcare provider (Aim 3) will occur in a private conference room at the IHS Zuni Comprehensive Health Center. The participant surveys (Aim 4) will be interviewer-led and will be done over the phone. The intervention sessions and associated surveys (Aim 8) will be conducted at the Zuni Health Initiative's center. The options will be provided to the participants so they can decide what the best is for them.

9. Resources Available

9.1. *Study Staff*

9.1.1. Shiraz I. Mishra, MBBS, PhD, Principal Investigator: Dr. Mishra is Professor at the University of New Mexico (UNM), Department of Pediatrics and Family and Community Medicine. Dr. Mishra is a health services researcher, with a strong methodological, intervention research, and program development background. His research is based on the socio-ecological and community-based perspectives, which provide multidisciplinary and multifactorial frameworks for community-based chronic disease prevention and control research. Guided by these perspectives, he has conducted community-based participatory descriptive and evaluative health disparities research using mixed methods (including quantitative surveys, and qualitative focus groups and semi-structured interviews) with a special emphasis on the primary and secondary prevention and control of cancer, especially focusing on breast, colorectal, and cervical cancers. In addition, he has conducted systematic review and meta-analysis of the literature examining the effects of exercise interventions on health related quality of life among cancer survivors. He has conducted participatory prevention research in collaboration with underserved communities, those from diverse racial/ethnic backgrounds, those who lack economic resources, and rural communities. Dr. Mishra has published extensively on research on access to and utilization of prevention and

control services and the efficacy of prevention interventions. He has received funding from NIH and private foundations and has served as reviewer on numerous NIH study sections.

9.1.2. Ursa Brown-Glaberman, MD, Clinical Co-Principal Investigator: Dr. Brown is an Assistant Professor in the UNM Department of Internal Medicine, Division of Hematology/Oncology. She is a board certified and practicing medical oncologist. Her interest lies in the treatment of solid tumors with a focus on breast and gastrointestinal cancers. Her research has focused on the development of prognostic and predictive biomarkers to guide the use of novel therapies. She is actively involved in the conduct of clinical trials, serving on the Protocol Monitoring and Review Committee and leading the Breast Cancer Clinical Working Group at UNM CCC.

9.1.3. Kevin English, DrPH, Co-Investigator: Dr. English is the Director of the Albuquerque Area Southwest Tribal Epidemiology Center (AASTEC) at the Albuquerque Area Indian Health Board (AAIHB). Dr. English is a public health researcher, with over a decade of experience in cancer control intervention research design, implementation and evaluation with American Indian communities. Dr. English possesses expertise in both qualitative and quantitative research methodologies. Dr. English currently leads the implementation of a national demonstration program aimed to build the capacity of tribal community health workers to engage in colorectal cancer control initiatives in American Indian communities. All of these research endeavors have been guided by the principles of community-based participatory research (CBPR) and impart a socioecological lens to understand, address and ameliorate public health disparities witnessed among American Indians. Working directly for American Indians within the context of an intertribal organization has allowed Dr. English to establish significant rapport and trust with this population where cancer remains highly sensitive and stigmatized and distrust of researchers is commonplace. Dr. English has received funding from NIH and other federal and state agencies and private foundations.

9.1.4. Andrew Sussman, PhD, MCRP, Co-Investigator: Dr. Sussman, is an Assistant Professor in the Department of Family and Community Medicine and Director of the Behavioral Measurement and Population Sciences Shared Resource at the University of New Mexico Cancer Center. Dr. Sussman has designed and led numerous qualitative and mixed method research studies. His research focuses on primary health care service delivery and patient-provider counseling dynamics among health disparity populations in New Mexico. The majority of this research has been conducted in outpatient primary care and community settings throughout New Mexico, mostly in predominantly Hispanic and American Indian tribal communities. Given this focus, he has extensive experience in participatory and community engaged approaches to research. He has over 30 publications in these research areas.

9.1.5. Joseph Rodman, Co-Coordinator: Mr. Rodman is Grade 13 Research Scientist with the Behavioral Measurement and Population Sciences Shared Resource at the University of New Mexico Cancer Center. Mr. Rodman will assist with coordinating the multiple activities proposed in the project, including obtaining regulatory approvals and ensuring compliance, coordinating the Advisory Panel meetings, assisting in the resource scan, assisting with analysis of the qualitative data, assisting with programming surveys in the iPads, and providing logistical support for data collection, data management, and data analysis.

9.1.6. V. Shane Pankratz, PhD, Co-Investigator and Biostatistician: Dr. Pankratz is the Director of the Biostatistical Shared Resource at the University of New Mexico Cancer Center, and a Professor in the Department of Internal Medicine. He is currently a member of the NAME Study Section of the NIH. His research interests are varied, focusing primarily on drawing appropriate inferences from population-based, longitudinally-collected data. He has extensive experience collaborating in a wide variety of research projects, including those focused on developing, implementing, and evaluating interventions for the control of cancer

and other chronic diseases. This includes recent work on PCORI-funded projects in the Zuni Pueblo that focus on evaluating a model of home-based kidney and diabetes care. The bulk of his expertise is in designing studies and in drawing quantitative inferences from them, as is evidenced by his extensive publication history, and he will apply this expertise to enhance the capture and summary of the data obtained throughout the multiple phases of this research study.

9.1.7. Nicholas Edwardson, PhD, MS, Co-Investigator: Dr. Edwardson is an Assistant Professor in the School of Public Administration at the University of New Mexico and is also a Senior Fellow of the Robert Wood Johnson Foundation Center for Health Policy. His research focus is innovation implementation in healthcare—including statistical quality methods, cost-effectiveness, and psychometrics/survey design. Prior to joining the faculty at UNM, Dr. Edwardson was the Assistant Director at the Center for Health Organization Transformation (CHOT)—a National Science Foundation Industry-University Cooperative Research Center based out of Texas A&M University, Georgia Tech, Northeastern University, Penn State, and University of Alabama at Birmingham.

9.1.8. Prajakta Adsul, MBBS, MPH, PhD, Co-Investigator: Dr. Adsul is an Assistant Professor in the Division of Epidemiology, Biostatistics, and Preventive Medicine in the Department of Internal Medicine at the University of New Mexico. Her research involves testing implementation strategies at multiple levels from a health services perspective to understand behavior change.

9.1.9. Mikaela Kosich, Biostatistician and Data Manager. Ms. Kosich is a Biostatistician and Data Manager for the UNMCCC Biostatistics Shared Resource.

9.1.10. Judith Sheche, Research Manager. Ms. Sheche, Zuni, is Research Manager at the UNMCCC.

9.1.11. Cheyenne Jim, Health Educator. Ms. Jim, Navajo, is a Health Educator at the Albuquerque Area Southwest Tribal Epidemiology Center.

9.2. When applicable, describe which licensed physicians/providers will be responsible for medical decision-making and ordering and evaluation of necessary diagnostics and therapeutics.

9.2.1. Not applicable

9.3. Other resources available to conduct the research

We have assembled an experienced research team led by Dr. Mishra and assisted by Dr. Sussman through the UNM Comprehensive Cancer Center's Behavioral Measurement and Population Science Shared Resource. Investigators have sufficient time and resources to complete the proposed study. All participating researchers have undergone updated human subjects training.

10. Prior Approvals

Upon departmental approval (from the UNM Comprehensive Cancer Center's PRMC), the departmental approval form is completed and uploaded to Click IRB under "supporting documents".

11. Multi-Site Research

N/A – UNM is the only site involved in this project.

12. Study Procedures

Aim 1: Develop a sustainable multi-directional, participatory collaboration ("community collaborative") between the Zuni tribal leadership, Zuni stakeholders (i.e., Health and Wellness program directors and Community Health Representatives [CHRs], cancer survivors), IHS Zuni Comprehensive Health Center, Albuquerque Area Southwest Tribal Epidemiology Center (AASTEC), and the UNM Comprehensive Cancer Center (UNM CCC).

We will develop a participatory "community collaborative" between the Zuni tribal leadership, Zuni stakeholders and local organizations (i.e., Health and Wellness program directors, CHRs, cancer survivors), healthcare providers (i.e., IHS Zuni Comprehensive Health Center), a tribal non-profit organization (i.e., AASTEC), and UNM CCC to develop and implement a cancer prevention and control research agenda. The collaborative will ensure a non-hierarchical partnership model necessary for research with AIs. We will constitute a 9-member Advisory Panel, representing all the entities listed above. The Panel will meet bimonthly and actively participate to: define education and research needs for the community and clinic members, assist in developing qualitative data collection instruments, assist in documenting resources available for cancer prevention and control research, constituency check inferences based on the qualitative data, prioritize cancer prevention and control needs identified through data obtained through Aims 4 and 5, and develop a research agenda for evidence-based intervention research that address cancer health disparities in Zuni. We will (1) build on the various stakeholders' strengths and integrate our respective knowledge and expertise, and (2) support an inter-dependent partnership, with a long-term commitment for mutually beneficial co-learning and capacity enhancement. Each member will receive a $100 merchandise card per meeting for their participation on the Advisory Panel.

Aim 2: Empower and develop capacity (using the Freirean educational pedagogy for adult learning) among Zuni people to participate in relevant cancer control education and research.

We will educate and train all Zuni CHRs who express an interest about cancers of the breast, CR, cervix, and prostate. Dr. Kevin English from the Albuquerque Area Southwest Tribal Epidemiology Center (AASTEC) will lead the initial 3-day training. We will provide three 2-day refresher trainings every six months. The training modules will include: cancer (breast, CR, cervical, and prostate) among AIs; anatomy of the female breast and reproductive system, digestive system, male reproductive system; breast, CR, cervical, and prostate Cancer 101; screening guidelines; risk factors; and treatment and management approaches. The teaching approaches will include digital stories, PowerPoint presentations, anatomical models, vignettes, and narratives. Following the education and training regarding the four cancers, we will hire and train four (4) student CHRs in the conduct of qualitative research. We will train the CHRs in basic research methods including recruiting participants, facilitating focus groups, conducting semi-structured in-person interviews, analyzing qualitative in data analysis, and administering surveys. We will provide this training over 2 days. We will offer the Cancer 101 and research trainings at the Native Health Initiative's office located in the Zuni Pueblo.

We will utilize principles of Freire's empowerment pedagogy[37] to provide the education and training. The pedagogy provides a model to conduct education and nurture new skills by defining attributes of an ideal educational environment, the mode of effective education, and the incorporation of cultural and socio-ecological sensitivities within the educational context. The pedagogy, based on the problem posing method of learning, emphasizes dialogue and reciprocity. In this method, the educator (Dr. English) will present the CHRs with a particular situation as a problem to be solved by the group. It is anticipated that the CHRs will internalize and evaluate critically the information they receive in the course of participating in an open dialogue with the educator, i.e., interactive exchange of knowledge. In addition, they are invited to introduce into the educational setting current environment and life circumstances that affect, in this study, the risk for cancers of the breast, CR, cervix, and prostate; challenges for completing recommended screening tests. Dr. English will empower the CHRs to make the problem of avoiding cancer their own problem instead of his problem. Through this strategy, Dr. English will involve himself in an interactive process that allows him to gain more information about the beliefs and prevention issues for the four cancers while at the same time allowing the CHRs to be actively involved in a problem-solving process that leads to improved health.

Aim 3: Assess cancer control needs of the Zuni people regarding the screen detectable cancers and resources available at the Indian Health Service (IHS) Zuni Comprehensive Health Center to provide screening services.

We will conduct focus groups[38] with purposively sampled eligible participants. Eligible participants will include those who are not compliant with U.S. Preventive Services Task Force screening guidelines for the three cancers[39-41] and those who are eligible for prostate cancer screening. For breast cancer this would include AI women aged 50 to 74 at average risk for breast cancer who have never had a mammogram or have not had a mammogram within the past two years. For CR cancer, this would include men and women at average risk for CR cancer aged 50 to 74 and never had a fecal occult blood test (FOBT) or fecal immunochemical test (FIT) or a colonoscopy, or not had a FOBT or FIT test in the past year, or no colonoscopic exam in the past 10 years For cervical cancer this would include women at average risk for cervical cancer aged 21 to 65 who have never had a cytology (Pap smear) or had a Pap smear more than 3 years ago; or women aged 30 to 65 who have never had screening with a combination of cytology and human papillomavirus (HPV) testing or no combination testing in the past five years. For prostate cancer, this would include men over the age of 50 years.

We will conduct up to 15 focus groups, up to 5 focus groups each among the following age/gender groups: Women aged 50-75, men aged 50-75, Women aged 21-49. The focus group interview guides are included as an appendix entitled "FocusGroupGuide(Women50-75)_2018_08_17_V1; FocusGroupGuide(Men50-75)_2018_08_17_V1; FocusGroupGuide(Women21-49))_2018_08_17_V1" and contains stem questions in the following areas: 1) knowledge about the respective cancer, 2) belief and attitudes regarding preventive behaviors in general, and cancer prevention in particular, 3) individual and social factors that facilitate and impede reducing risk and promoting better health, 4) factors that pose barriers obtaining screening exam,5) factor that can facilitate obtaining a screening exam, and 6) strategies that can enhance screening behavior. We will invite 12-15 eligible persons for each of the focus groups and, with potential attrition, we anticipate about 8-12 persons per focus group. Before the discussion, participants will undergo informed consent using a consent letter requiring no documentation of written consent and we will obtain permission to digitally audio-record the session. We anticipate that each group session with women aged 21-49 will last about 90 minutes, and the group sessions with women and men aged 50-75 will last about 2 hours and we will digitally audio-record for subsequent transcription and analytic review. We will also collect baseline socio-demographic (age, sex, race/ethnicity, marital status, educational and employment status, health insurance coverage, primary language spoken at home, health literacy, and primary source of healthcare) information from each participant. See appendix entitled "Socio-DemographicSurvey(Zuni))_2019_02_11_V4". Before starting the focus group, we will obtain written informed consent (see "ConsentForm_FocusGroupParticipation(Women-Men50-75)_2018_10_01_V2" and ConsentForm_FocusGroupParticipation(Women21-49)_2018_10_01_V2". Following the discussion, women participating in the focus groups inquiring only about cancer of the cervix (Women Aged 21-49) will receive a $50 merchandise card in appreciation of their time. Women and men participating in focus group inquiring about multiple cancers (i.e., the Women Aged 50-75 and Men Aged 50-75 groups) will receive a $75 merchandise card in appreciation of their time. The slightly higher amount for the latter two groups is an acknowledgement of the additional discussion time that may be needed for these groups.

We will conduct up to 3 focus groups with members of the Tribal Advisory Panel (TAP). We will invite 12-15 eligible TAP members for each of the focus groups and, with potential attrition, we anticipate about 8-12 persons per focus group. The focus group will document individual, social, systemic, and cultural barriers/promoters to obtaining cancer screening services. We will also elicit their perspectives on evidence based strategies we can implement in Zuni that could potentially enhance cancer screening uptake (NOTE: We will submit a modification request for review and approval the Focus Group Guide

specifically developed for the TAP member focus group.). We will collect baseline socio-demographic information from the participants, using the instrument previously approved for use with providers (see below). Before starting the focus group, we will obtain written informed consent (see "ConsentForm_FocusGroupParticipation(TAPmembers)_2019_11_08_V2") and permission to digitally audio-record the focus group. We anticipate the focus group to last 45-60 minutes. Following the discussion, the TAP members will receive a $50 merchandize card in appreciation of their time or if federally employed, reimbursement for food and travel expenses.

We will conduct up to 3 focus groups[38] with purposively sampled eligible healthcare providers from the IHS Zuni Comprehensive Health Center. We will invite 12-15 eligible healthcare providers for each of the focus groups and, with potential attrition, we anticipate about 8-12 persons per focus group. The focus group will document resources available for providing cancer screening services, and structural and system-level promoters and barriers to providing screening. The focus group with the providers will also inquire about relevant MHOF constructs such as structural, social, cultural, and contextual influences on cancer screening. See appendix entitled "FocusGroupGuide(Provider)_2018_09_26_V1". We will collect baseline socio-demographic information from the participants. See appendix entitled "Socio-DemographicSurvey(Providers-TAPmember)_2018_10_05_V2". Before starting the focus group, we will obtain written informed consent (see "ConsentForm_FocusGroupParticipation(Provider)_2019_11_08_V2") and permission to digitally audio-record the focus group. We anticipate the focus group to last 45-60 minutes. Following the discussion, the providers will receive a $50 merchandize card in appreciation of their time or if federally employed, reimbursement for food and travel expenses.

We include month and year of birth (instead of age or full date of birth) and zip code in these demographics surveys because this is a Cancer Prevention study overseen by the Cancer Center's DSMC and therefore required to provide limited accrual information to the NCI Clinical Trials Reporting Program (CTRP). The CTRP requires the following fields be provided per participant: Study ID, Zip Code, Country of Residence, Month of Birth, Year of Birth; Gender; Ethnicity; Race.

Aim 4: Evaluate the cancer-related knowledge, attitudes, and self-reported cancer screening practices using quantitative survey methods among a convenience sample of Zuni people.

We will use data from the focus group discussions to develop a survey instrument to document cancer-related knowledge, attitudes, self-reported cancer screening practices, and preferences for intervention strategies to enhance screening services (see "Survey_Men50-75_2020_06_22_V1", "Survey_Women21-49_2020_06_2_V1", and "Survey_Women50-75_2020_06_22_V1"). We will also collect socio-demographic (age, sex, race/ethnicity, marital status, educational and employment status, health insurance coverage, primary language spoken at home, health literacy, and primary source of healthcare) information. Unfortunately, the three surveys listed above did not have a question to determine age of the participants. To address this oversight, we have revised the 1-page Contact Sheet (see "ContactSheet_2021_01_07_V2) by adding a question on age. We have completed surveys with about 140 participants across the three age/sex strata. Using the same question as in the Contact Sheet, we will re-contact these participants to collect information on their age. Upon approval, we will administer this survey over the phone to about 250-280 men and women age-eligible for screening, so as to have about 50-60 women 21-49 years (cervical cancer), 100-110 men 50-75 (CR and prostate cancers) and 100-110 women (breast, CR, and cervical cancers). The sample size for women aged 21-49 eligible for the survey with a focus on questions only on cervical cancer is lower in light of the fact that the survey of women aged 50-75 will include questions regarding cancer of the cervix, besides cancers of the breast and CR. We will use validated questions from the Behavioral Risk Factor Surveillance Survey, the National Health Interview Survey (Cancer Supplement), our previous research, and new questions based on findings from the focus group discussions. We will setup the

survey on REDCap. Before starting the survey we will read the consent letter requiring no documentation of written consent (see "Consent_Survey_Men50-75_2020_06_22_V1", "Consent_Survey_Women21-49_2020_06_22_V1", and "Consent_Survey_Women50-75_2020_06_22_V1"). The survey will average about 20 minutes to complete for men 50-75 years and women 21-49 years, and 40 minutes to complete for women 50-75 years. Men 50-75 years and women 21-49 years will receive a $25 merchandise card, and women 50-75 years will receive a $50 merchandise card in appreciation of their time. We will mail the merchandise cards to the participants (see "ThankYouNote_2020_06_22_V1"). If the participants request, we will mail the Consent Letter along with the merchandise card.

Aim 5: Integrate data to better understand cancer prevention and control challenges for the Zuni people:

a. Ascertain cancer burden, risk factors, and screening rates among the Zuni people.
b. Synthesize data collected as part of Aim 3b on resources available in the community, IHS Zuni Comprehensive Health Center, and at UNM CCC that can address the Advisory Panel-identified cancer prevention and control priorities.
c. Synthesize data collected as part of the qualitative and quantitative research (Aims 3a and 4).

We will integrate data from three sources (i.e., state/national databases [Aim 5a], assessment of cancer prevention and screening resources available [Aim 5b], and qualitative research [Aim 5c]) to better understand cancer prevention and control needs for the Zuni people. Prior to compiling any data, we will consult with the Advisory Panel regarding its preferences on the types, extent, and details of data to help prioritize Zuni-specific cancer control needs. First (Aim 5a), we will have Dr. Wiggins (Director, NMTR) analyze and present to the community collaborative Zuni-specific and comparative data on cancer epidemiology. These data will include cancer incidence, mortality, 5-year survival, stage-at-diagnosis, and trends over time for Zuni and also compared with other AIs and racial/ ethnic groups in NM. We will also compile and present data on risk factor and rates of screening for screen-detectable cancers obtained from the Albuquerque Area IHS Government Performance and Results Act data, NM Indicator-Based Information System and the Behavioral Risk Factor Surveillance System. We will note limitations of these databases in accurately collecting and reporting data about tribal communities. Second (Aim 5b), we will synthesize data collected as part of Aim 3b on resources available in Zuni, IHS Zuni Comprehensive Health Center, and at UNM CCC to address the Advisory Panel-identified cancer prevention and control priorities. These resources will include, but not be limited to, availability of and capacity for: screening services; cancer risk reduction health and wellness programs; trained medical and non-medical personnel for cancer prevention and control activities; follow-up diagnostic, treatment and management facilities; and IT and database management resources. Third (Aim 5c), we will synthesize and integrate qualitative and quantitative research data collected as part of Aims 3a and 4. These data will provide insights about Zuni residents' perspectives on cancers of the breast, CR, and cervix. Specifically, the qualitative data will shed light in the following areas: 1) knowledge about the respective cancer, 2) belief and attitudes (cultural, social, behavioral) regarding preventive behaviors in general, and cancer prevention in particular, 3) individual and social factors that facilitate and impede reducing risk and promoting better health, 4) factors that pose barriers and facilitate obtaining screening exam, 5) social determinants of health, and 6) strategies that can enhance screening behavior.

Integration of data from these three sources will help better understand needs and challenges for Zuni-specific cancer prevention and control efforts. Coupled with this understanding, the granular data will be foundational in the prioritization of needs, and the development and implementation of tailored and targeted intervention trials.

Aim 6: Develop a cancer prevention and control research agenda for tribal communities in rural NM:

a. Develop a Zuni-specific comprehensive plan for research and evidence-based interventions in cancer prevention and control.
b. Design a model, based on the lessons learned, for a collaborative cancer prevention and control research agenda for tribal communities across rural NM.

Aim 6a: The TAP will review the multi-component data analyzed as part of Aims 4 and 5 to set priorities for the Zuni-specific cancer prevention and control research agenda. The TAP will set priorities based on defining cancers that have the biggest impact on the Zuni community. Since this will be a participatory process, it is difficult to *a priori* identify algorithms that we will use to define and set the priorities. The priorities could be set based on cancer(s) with a high incidence but low mortality above or below cancer(s) with low incidence but high mortality; changing trends in incidence, mortality, and 5-year survival; treatment costs; length of stay in a hospital; established evidence-based primary or secondary prevention and control strategies recommended by The Community Guide and USPSTF; evidence for preventing cancer(s) (i.e., modifiable risk factors); and availability of community and healthcare resources.

Aim 6b: We will assess challenges and facilitators to developing the Zuni-specific cancer prevention and control research agenda. The assessments will document: (1) aspects of developing the collaborative (i.e., collaboration between entities with different institutional missions, representative participation, trust building, engagement). (2) development and sustenance of research capacity through focused and time-limited training and education. (3) compilation, analysis, presentation, and critical appraisal of data on cancer control needs that may be limited by small sample sizes. (4) defining and setting cancer prevention and control research priorities within the context of uncertainties regarding availability of and access to adequate resources in rural NM. Based on the lessons learned from this assessment, we will develop a model for translating and sustaining a cancer prevention and control research agenda across other AI tribes in rural NM. We will develop plans for cancer control research in collaboration with 11 additional tribal communities in the IHS Albuquerque Area that are situated in RUCA categories 7-9.

Aim 7: Using participatory approaches by engaging the TAP, finalize multilevel/ multicomponent intervention strategies to increase provider delivery of, community access to, and community demand for screening for the screen-detectable cancers.

A. Data mapping and participatory engagement of the TAP: As part of the Aims 3 and 4, we are conducting an environmental scan of resources available at the health center to offer screening services, and structural/system-level promoters and barriers to providing screening. We will map and present these data, along with evidence-based recommendations from The Community Guide, to the TAP for participatory input on appropriate multilevel/multicomponent intervention strategies that can enhance screening. The overall focus of our intervention model, per The Community Guide, is on intervention strategies that fall into 3 categories. First, *increase community access* by reducing structural/systemic barriers (e.g., reduce administrative barriers, patient navigation, assist in appointment scheduling, set up alternative screening sites, and modify screening clinic hours). Second, *increase community demand* using culturally, linguistically, and health literacy appropriate group education, 1-on-1 education, client reminders and incentives, mass media, and small media (i.e., educational brochures). Third, *increase provider delivery* of screening services through, improved provider recommendations, provider reminder/recall systems, and shared-decision making tools. Evidence suggests that a combination of strategies from each category leads to greater effects. We will conjointly work with the TAP to select evidence-based intervention strategies (at least 1 strategy from at least 2 [preferably all 3] categories) that can best address

barriers identified through the qualitative and quantitative research, can leverage existing resources at the health center, and meet the cancer control needs of the Zuni people.

B. Small media: We will develop small media (i.e., educational brochure, factsheet, and flipchart) on the 3 cancers. The Community Guide recommended strategies to increase demand for and access to screening require the ability to understand cancer risk, screening benefits, health system navigation — all to make informed decisions and take appropriate action. We will use small media to convey this information. We will operationalize the MHOF constructs such as knowledge, susceptibility, severity, norms, and self-efficacy in the small media. We will recruit 12-15 participants for two focus groups for each of the three cancers (up to 6 focus groups total), assuming some degree of attrition. In accordance with COVID-19 mitigation protocols, we may conduct the focus groups on ZOOM. If the Pueblo of Zuni's Tribal Administration permits in-person gatherings for research purposes, we will make efforts to find a room large enough to meet in person, while ensuring appropriate social distancing measures. If we conduct the focus groups over ZOOM, prior to the meeting all participants will receive a packet containing the Consent Letter (see "ConsentLetter_SmallMediaFG_2021_11_02_V4") and the brochures and factsheets on CR, breast, and cervical cancers, respectively (ColorecalCancer_Brochure_2021_03_19_V1, ColorectalCancer_Factsheet_2021_03_19_V1, BreastCancer_Brochure_2021_03_19_V1, BreastCancer_Factsheet_2021_03_19_V1, CervicalCancer_Brochure_2021_03_19_V1, CervicalCancer_Factsheet_2021_03_19_V1). Irrespective of the mode used to conducted the focus groups, Zuni students and research staff specially trained to lead focus groups will facilitate the sessions that will meet for approximately 45-60 minutes. Before the session, we will review the consent letter and inform participants that we will digitally audio-record the session. At the start of the session, we will distribute a brochure on CR cancer developed for an ongoing project (NCI/NIH: R01CA192967; Mishra, PI) and give participants several minutes to thoroughly review the document. In addition to querying about the MHOF, we will pose questions about the degree to which the brochure "fits" with traditional beliefs about health, graphic layout, artwork, word usage, using a discussion guide ("FocusGroupQuestions_SmallMedia_2021_03_19_V1"). Once we complete the discussion around the brochure and factsheet on CR cancer, we will follow a similar protocol for discussions on the brochures and factsheets on breast and cervical cancers. We will focus on one cancer-type related materials per session. However, if time permits, we may discuss more than one cancer type per session. Following the session, participants will receive a $50 merchandize card.

We will follow the same procedure as the brochure and factsheets mentioned above for the educational flipcharts. Being cognizant of the Pueblo of Zuni's COVID-19 protocols, the focus groups will be held either in-person in a room large enough to ensure social distancing or held virtually via Zoom. The study team members will provide participants packets that contain the Consent Letter (ConsentLetter_SmallMediaFG_2021_11_02_V4) and the flipchart for each of the three cancers: colorectal, breast and cervical (Colorectal Cancer Flipchart_2021_11_02_V1, Breast Cancer Flipchart_2021_11_02_V1, Cervical Cancer Flipchart_2021_11_02_V1). We will recruit 12-15 participants for three focus groups for each of the three cancers (up to 9 focus groups total), assuming some degree of attrition. We expect each focus group to be approximately 45-60 minutes and will be conducted by Zuni students and research staff. We will ask similar questions to those used for the brochure and factsheet on how well the flipchart "fits" with traditional beliefs about health, graphic layout, artwork, word usage, using a discussion guide (FocusGroupQuestions_SmallMedia-Flipchart_2021_11_02_V1). Following the session, participants will receive a $50 merchandize card.

For these small media documents, focus group participants recommended changes to make these documents to be more specific to the Pueblo of Zuni. This includes a testimonial statement in the Zuni language for cervical, breast, and colorectal brochures; images/photos that are specific to the tribe; and artwork from a Zuni artist. Additional edits were recommended for theme colors for each cancer and larger font sizes due to the target population for breast and colorectal cancers (age 45-

75). Participants recommended the creation of a poster that contains the same information as the factsheets to be placed in public places/settings, making three products for each cancer: brochure (BreastCancer_Brochure_2022_08_26_V2, CervicalCancer_Brochure_2022_08_26_V2, ColorectalCancer_Brochure_2022_08_26_V2), factsheet (BreastCancer_Factsheet_2022_08_26_V2, CervicalCancer_Factsheet_2022_08_26_V2, ColorectalCancer_Factsheet_2022_08_26_V2) and poster (BreastCancer_Poster_2022_08_26_V1, CervicalCancer_Poster_2022_08_26_V1, ColorectalCancer_Poster_2022_08_26_V1).
Because of participant and TAP member request following the focus groups, we will be mailing out the 3 brochures (breast, cervical, and colorectal) to all postal mailboxes in the Pueblo of Zuni prior to the intervention. There is one post office in the Pueblo that serves the households of Zuni, where all mail for residents are delivered. The study team will work with a local printer that will print and mail these brochures to each occupied (active) mailbox at the Zuni post office, approximately 1,530 mailboxes. We will not request any identifiable information from the tribe to complete this mailing rather we will use a method of mass mailing that will direct the mailout to "postal customers", where the postmaster will deliver these brochures to active mailboxes in the Zuni Pueblo and appropriate zip code.

Aim 8: Pilot test (including qualitative methods) the multilevel/ multicomponent culturally and linguistically appropriate intervention strategies on outcomes such as: impact on screening practices; feasibility of implementation and acceptability of the intervention; and cost effectiveness of the intervention.

We will pilot test the intervention (INT) to document its: impact on screening practices; feasibility/ acceptability; promoters/barriers to screening; effect positive changes on the MHOF constructs; and cost effectiveness. We will use quantitative followed by qualitative (focus group) mixed methods. We will recruit participants based on gender and age for cancer-specific screenings. In all, we will have up to 60 men age 45-75 (for CR cancer INT) 60 women age 45-75 (for breast [50-75 only], CR, and cervical cancer INTs) and 30 women age 21-44 (for cervical cancer INT). We will offer each group the specific cancer INT(s).

Implementation of quantitative (survey) data collection to document INTs' impact on screening. We will contact (in-person or phone call) interested participants and provide them with a study description (StudyDescription_Intervention_2022_10_26_V1). If participants are interested, the study will continue with eligibility (Eligibility Screener_Intervention_2023_02_02_V2). If participants are eligible, they will provide contact information (ContactSheet_Intervention_2022_10_26_V1) for the purposes of scheduling the study activities. The study will provide a packet that will contain the consent letter (ConsentLetter_InterventionTesting_2023_02_02_V4) that describes the study, PI contact information, description of the overall benefits and risks of participation, and dates for the study activities (i.e., baseline [BL] survey, INT session, post-intervention survey). The contact sheet will also ask participants if they wish to be contacted for future studies. If participants wish to be contacted, this will form our convenience sample for recruitment for the qualitative data collection for Aim 8 (focus groups). We will be using a consent letter format to continue to minimize COVID-19 exposure and risks for both community members and study team. The study is also minimal risk (surveys and educational session on specific age-gender cancer through the use of cancer specific flipcharts and small media) and encourages standard of care. The packet will also contain a scheduling card to inform participants about the date and time for the next project activity (baseline survey, INT session, post-intervention survey, focus group). Zuni students and staff will administer the surveys. We will conduct 2 waves of outcomes evaluation surveys: BL and at follow-up (6-8 months post-INT). [NOTE: We will submit the surveys to the HRRC and SWTIRB for review and approval prior to conduct of the surveys.]

We will administer BL and post-INT surveys in-person or over the phone and each will last approximately 20-30 minutes, dependent on the cancer specific survey (Baseline Survey_Men45-75_2023_02_02_V2, Baseline Survey_Women21-49_2023_02_02_V2, Baseline Survey_Women50-75_2022_10_26_V1, PostIntervention_Survey_Men45-75_2023_04_28_V1, PostIntervention_Survey_Women21-44_2023_04_28_V1, PostIntervention_Survey_Women45-75_2023_04_28_V1). Prior to each project activity, we will contact (phone or in-person) participants informing them of the date, time and place of the upcoming activity. During each project activity, we will confirm/update the participants' contact information. Between 6-8 months post-INT, we will remind (phone or in-person; at 3-monthly intervals), if necessary, participants to complete their screening exam. Participants that report completing their appropriate screening will be taken off the reminder call list.
For post-INT follow-up with participants starting at 6 months, they will be contacted by phone (either text or phone call) once a week over the course of three weeks. If no response from phone outreach, then two home visits will be made, over the course of two weeks. If participant does not respond after the two home visits, a note will be left for the participant with study team contact information (Intervention_participant note_2023_06_30). Following this, no further contact will be attempted to the participant from the study team. The participant will have until the end of their 8th month to complete their post-INT follow-up survey.

Implementation of qualitative data collection to documents promoters/barriers to screening. After the follow-up surveys, we will conduct up to 6 focus groups with those that indicated interest on the post-intervention survey. The focus groups will include participants based on gender and age for cancer-specific screenings. The results of the post-intervention survey question on focus group interest had yielded a low number of potential focus group participants, therefore we will be combining those reporting they are "adherent" (up to date on their screening) or were "not adherent" (not up to date on screening) for each age and gender specific group. Assuming some degree of attrition, we will recruit up to 10-12 participants per focus group. The purpose is to explore factors conducive to complete a screening (i.e., navigation, harm/ benefit assessment, norms and support, acceptability of the test, and self-efficacy). Among participants who did not complete any exam, we will inquire about barriers (i.e., social norms and support, acceptability, home-testing) and their potential solutions (see "FocusGroupGuide_education program_V1_2023_09_27"). Data collection and analysis procedures are similar to those described for small media development (Aim 7). Before the session, we will obtain consent (see "ConsentLetter-InterventionFG_2023_09_27_V3") and inform participants that we will digitally audio-record the session. We will provide a form following the FG to ask whether the participants received screening (FG screening question_V1_2023_09_27). Participants will not need to provide any other information other than this.
Based on a round of implementing focus groups, we will implement one-on-one interviews with participants as needed per gender and age for cancer specific screenings. Assuming some degree of attrition, we will recruit 5-7 individuals per cancer specific screening for interviews. The interviews will follow a semi-structured format with similar questions as the focus groups (InterviewGuide_education program_V1_2023_10_30). Before each interview, we will obtain consent (ConsentLetter-InterventionInterview_2023_10_30_V1) and inform participants we will digitally audio record the session.

Multilevel/multicomponent INT. The TAP will finalize the INT strategies (Aim 7). The overall INT will be bounded by contextual realities (rurality of the Zuni Pueblo, resources at the health center, budget for the project). With this context in mind, we could operationalize The Community Guide's recommended strategies that the TAP may plausibly identify as follows: To increase community access, we could: (a) Identify a point-person (i.e., Public Health Nurse) at the health center who will triage participants to and schedule them for appropriate screening(s). (b) Remind (phone or in-person) participants (between post-INT and follow-up) to complete their screening exam(s), offer assistance in

scheduling a screening appointment and a ride to the health center. These strategies would reduce administrative barriers, navigate participants, and assist with transportation and in scheduling an appointment. To increase community demand, we could consider: (a) Small media. (b) 1-on-1 education (supplemented by the small media) by the project's staff. (c) Reminders between post-INT and follow-up. (d) Cognitive-behavioral group education and incentives. To increase provider delivery, we could: (a) Reduce health center-specific systemic barriers by identifying a point-person to promote and facilitate screening services.

Implementation of the INT. We will implement the INT over a 1-hour long session following the BL. The INT session will consist of an educational session that is approximate 1-hour long, dependent on the cancer and will be conducted in-person with COVID-19 safety precautions. This educational session will use flipcharts that teach participants about a specific cancer, risks, protective factors, cancer specific screening, stages of cancers and survival (Breast Cancer Flipchart 2022_10_26_V2, Cervical Flipchart_2022_10_26_V2, Colorectal Flipchart_2022_10_26_V2). The flipcharts will be accompanied by the small media documents, factsheets and brochures (previously HRPO approved).

Cancer screening, analysis, reporting, and follow-up of test results. The health center will analyze all screening exams. The health center's provider will notify participants of their results.

13. Data Analysis

13.1. The patient questionnaires will be analyzed utilizing approaches consistent with each data source. The structured questions will be exported from REDCap to a statistical software package for analysis. The qualitative responses to the questionnaire will be digitally recorded and transcribed for standard content analysis. The UNMCCC's Behavioral Measurement and Population Science Shared Resource will support the qualitative and quantitative data analysis efforts.

13.2. Quantitative Data Analysis (Aims 4 and 8): We will use descriptive statistics to characterize participant characteristics and their knowledge, attitude, screening practices, and preferred intervention strategy. We will use univariable and multivariable logistic regression analyses, with inclusion of modeling variables informed by the MHOF, to assess the relationship between socio-demographic variables, knowledge, and attitudes and beliefs on screening behaviors (Aim 4).

For Aim 8, for the primary outcome (completion of cancer screening), we will compare the number of cancer screening approaches (i.e., screenings for breast, CR, and/or cervical cancers) undertaken by study participants (based on age and gender), offset by the number of possible screening tests, using Poisson regression approaches between those who are and are not receiving active intervention. This will enable the estimation and comparison of screening uptake between treatment arms, even when there are different numbers of possible screening tests for groups of participants. We will account for within-cluster correlations using generalized estimating equations, and we will explore the impact on screening uptake of patient characteristics (e.g. sex) using fixed effects.

13.3. Qualitative Analysis (Aims 3, 7, and 8): We will transcribe the audio recordings verbatim for use in the analysis. As part of the initial analysis, each team member will read the transcripts to identify recurring and new themes, especially along the constructs identified in the MHOF theoretical framework. We will proceed iteratively to develop a coded index of themes. The initial analysis will result in coding templates for the data. Once we reach consensus on the templates, we will import the transcripts into NVivo 10, a qualitative data analysis software program. Software-aided content analysis contributes to high reliability because rules for coding are explicit and consistently applied to the text. We will conduct the actual coding in NVivo and

review the first set of initially coded transcripts to ensure a high inter-rater reliability in the coding assignment. We will group occurrences of data into broad categories to guide the development of the themes within the conceptual model. We will create a master codebook as we assign specific codes and identify new themes. The codebook will link specific codes to passages in the transcripts. The team will keep detailed records of changes made to the coding scheme, including the rationale for the changes. As we code the transcripts, the codebook will become the central unifying document that summarizes the data. Once we complete this process, the data set will be ready for a secondary and more refined level of interpretive analysis by the research team to assess the relevance of anticipated issues as well as those that emerge during the process of data interpretation.

14. Provisions to Monitor the Data to Ensure the Safety of Subjects

N/A – this is a minimal risk study

15. Withdrawal of Subjects

Participants are able to withdraw from this study at any time. If a participant indicates they would like to withdraw, the research coordinators will note the withdrawal date and reason. As this study involves minimal risk, no additional procedures are necessary. The Principal Investigator may also choose to withdraw a participant from the study for failure to follow instructions.

16. Data Management/Confidentiality

16.1. We will protect the autonomy of the participants by informing them of the purpose of the study, and allowing them to opt out of participation without repercussion. We will maximize efforts to ensure confidentiality through the use of unique identification numbers (IDs). We will assign each participant an ID, which we will use to link the participant will all his/her study related materials. We will keep the data file linking the unique ID with the master list of ID code numbers and personally identifiable data in separate password-protected data files on a password-protected computer. Only trained study staff will have access to the master list.

16.2. We will need to include patient name and contact information (phone number and address) for involvement in the research study. This information will not be linked to the data and discarded once the participant either completes the survey or attempts have been made to do so.

16.3. We do not believe a Certificate of Confidentiality is necessary for this study as no specific and sensitive data are being collected.

16.4. Patient and provider survey responses will be stored on password protected, HSC computers only accessible to members of the authorized research team. No patient or provider identifying information will be linked to the data.

16.5. Data from the questionnaire will be both quantitative and qualitative. The quantitative data will be exported from REDCap to a survey analysis software package for further analysis. The qualitative data will be reviewed and imported into NVivo where it will be coded. The NVivo software will only be accessible to members of the authorized study team and will be password protected on HSC servers.

16.6. The loss of confidentiality through the transcripts and electronic database is therefore considered minimal.

16.7. We will store the transcribed data and those collected through the survey until the completion of all study activities, including publications, or for 3 years, whichever comes later.

16.8. No data will be transferred or transmitted to outside locations or entities.

16.9. No data will be collected, transmitted, and/or stored via the internet.

16.10. During the participant focus groups and interviews (Aims 3, 7, and 8), we will make audio recordings of the responses to further analyze these data. We will assess the transcribed documents upon return from the transcriptionist and remove any potentially identifying information. We will not be returning the recordings to the subjects for further review.

16.11. None of the data will include photographs.

17. Data and Specimen Banking

N/A – no specimens are being collected in the proposed project

18. Risks to Subjects

There are minimal risks to participants for participating in these study activities. Participants will be reminded that their survey is anonymous and that no identifiers will be attached to the answers they provide. While participants may feel uncomfortable sharing their thoughts on the survey or in a focus group setting, every effort will be made to provide an environment that is comfortable, non-threatening, and private. Participants will be reminded that they are not required to respond to any questions which are uncomfortable or otherwise unacceptable to them, and that they can withdraw participation at any time.

19. Potential Benefits to Subjects

No direct benefits to participants are expected.

20. Recruitment Methods

20.1. We will use purposive (Aims 3, 7, and 8: focus group) and convenience (Aim and 8: survey) sampling approaches to recruit participants. We will approach participants by direct contact via personal telephone contact and through announcements via flyers (see "Men 50-75 Recruitment Flyer_2018_10_05_V2", "Women 21-49 Recruitment Flyer_2018_10_05_V2", and "Women 50-75 Recruitment Flyer_2018_10_05_V2") posted at appropriate locations. We will provide participants written description of the study and their agreement to participate will be seen as tacit consent. We will seek a waiver for written consent. As previously stated, participants for Aim 4 (survey) will be recruited by placing/ distributing flyers (see "RecruitmentFlyer_Survey_2021_02_22_V4") to households selected from randomly identified streets in the Zuni Pueblo. In the recruitment flyer, we have requested participants call if interested in participating or to learn more about the study. For those who call, we will describe the study and inquire whether the potential participant wishes to participate in the study (see "StudyDescription_2020_06_22_V1"). If the potential participant is interested, we will determine whether the person meets the eligibility criteria (see "EligibilityScreener_2020_06_22_V1"). If the person is eligible and interested in participating in the survey, we will collect information to enable us to contact the participant for the survey and to mail the merchandise card (see "ContactSheet_2021_01_07_V2). Information collected on this sheet will be kept separate from the survey data and will only be used to contact the participant. The change in recruitment methods (no-contact distribution of flyers and determination of eligibility), conduct of surveys (over the phone), and distribution of the merchandise cards (via mail) are all done in response to COVID-19. We want to mitigate exposure to our research team and study participants. For Aim 8 (intervention), we will follow similar recruitment strategies by using convenience sampling. We will post and distribute flyers (Zuni Cancer Study_Intervention_flyer_2023_02_02_V2) in the Pueblo. We will also place/distribute flyers to households selected from randomly identified streets in the Zuni Pueblo. We have requested in the flyer that interested participants call the study phone number. In Aim

4, the study utilized a contact sheet (ContactSheet_2021_01_07_V2) that asked participants if they would like to be contacted for future research. As part of Aim 8's recruitment, we will follow-up with these previous participants that consented to being contacted to assess interest and eligibility for the intervention in addition to recruitment via flyers. We will provide potential participants a description of the study (StudyDescription_Intervention_2022_10_26_V1) and review eligibility criteria (Eligibility Screener_Intervention_2023_02_02_V2). If the person is eligible and interested in participating in the survey, we will collect information (ContactSheet_Intervention_2022_10_26_V1) to enable us to contact the participant for the study activities. This contact information will be kept separate from the baseline survey. To mitigate COVID-10 risks, the study would also be able to mail the merchandise cards via US Postal Service to participants using the mailing address on contact sheet. The contact sheet for the intervention (ContactSheet_Intervention_2022_10_26_V1) includes a question on whether participants would like to be contacted for future studies. For those participants that agree to be contacted, these participants will form our recruitment pool for the Aim 8 qualitative focus groups and interviews.

21. Provisions to Protect the Privacy Interests of Subjects

21.1. We will use purposeful sampling methods for the qualitative research focus groups proposed in Aims 3, 7, and 8. If a participant meets the eligibility criteria and agrees to participate, s/he will be scheduled for the informed consent and a focus group session. The participant will be informed that the focus group will last about two hours that s/he can terminate the participation at any time that s/he may decline to answer any question, that s/he will receive a merchandise card for participation in the focus group, and that all recordings and transcriptions will have personal identifiable information removed. As stated above, for Aim 3, women aged 21-49 participating in focus group on cervical cancer will receive a $50 merchandize card; and men and women aged 50-75 participating in focus groups inquiring about multiple cancers will receive a $75 merchandize card. For Aims 7, the focus group participants will meet for about 45-60 minutes and will receive a $50 merchandize card in appreciation of their time. For Aim 8, participants will receive a $50 merchandize card for their participation in the focus group.

21.2. We will recruit healthcare providers through the IHS Zuni Comprehensive Health Center for the qualitative research focus groups proposed under Aim 3. Before starting the focus group, participants will undergo informed consent and we will obtain permission to digitally audio-record the group session. The participant will be informed that the focus group will last about 45-60 minutes that s/he can terminate the participation at any time that s/he may decline to answer any question, that s/he will receive a $50 merchandize card for participation in the focus group, and that all recordings and transcriptions will have personal identifiable information removed.

21.3. We will conduct interviewer-led surveys to the participants, which they will complete over the phone.

21.4. All study data (transcripts, surveys) used for analysis will be de-identified of any personally identifiable information from the participants.

22. Economic Burden to Subjects

Subjects will bear no responsibility for costs related to this research.

23. Compensation

23.1. Each focus group participant will receive a merchandize card in appreciation of her/his time. For Aim 3, women aged 21-49 participating in focus group on cervical cancer will receive a $50 merchandize card; and men and women aged 50-75 participating in focus groups inquiring about multiple cancers will receive a $75 merchandize card. Each healthcare provider and TAP

members participating in the focus group will receive a $50 merchandise card in appreciation of her/his time. Each focus group with the physicians and TAP members is expected to take 45 to 60 minutes, therefore the amount of money is a reasonable amount of compensation. For Aims 7, the focus group participants will meet for about 45-60 minutes and will receive a $50 merchandize card in appreciation of their time. For Aim 8, the focus group and interview participants will meet for up to 2 hours and will receive a $50 merchandize card in appreciation of their time.

23.2. Each participant who completes the survey (Aims 8) will receive a $25 merchandise card in appreciation of their time. Each survey will take an average about 20 minutes to complete, therefore the amount of money is a reasonable amount of compensation. For Aim 4, surveys among men 50-75 years and women 21-49 years will average about 20 minutes and they will receive a $25 merchandise card; whereas, the survey with women 50-75 years will average about 40 minutes and they will receive a $50 merchandise card … amounts that are reasonable for the time provided to participate in the study.

23.3. Each participant who completes the intervention session will receive a merchandize card at the end of the educational session. Men 45-75 years and women 21-44 years will receive $25 merchandize cards since they are eligible for one educational session on one cancer. The educational session will be administered over 1 session, about 1-hour long. Women 45-75 years will receive $50 merchandise cards because they may be eligible for screening on 2-3 different cancers (breast, cervical, colorectal). These educational sessions will be administered over 1-2 sessions, about 1-hour each.

23.4. Each member of the advisory panel will receive a $100 merchandise card per meeting attended, up to 4 meetings over the life of the study. Each meeting is expected to take no more than 2 hours, therefore the amount of money is a reasonable amount of compensation for their level of expertise and experience.

24. Compensation for Research-Related Injury

N/A – no compensation is offered for research-related injury. This is a Minimal Risk study.

25. Consent Process

Waiver or Alteration of Consent Process (consent will not be obtained, required element of consent will not be included, or one or more required elements of consent will be altered)

- We will be seeking a waiver of consent

26. Documentation of Consent

26.1. We are requesting a "Waiver of Documentation of Consent" for all participants in this study

27. Study Test Results/Incidental Findings

27.1. **Individual Results*:*** We have no plans for directly sharing results with study participants. We will share results aggregate level qualitative (focus group and interview) and quantitative (survey) data as summary reports for the providers.

27.2. **Incidental Findings*:*** N/A.

28. Sharing Study Progress or Results with Subjects

N/A – no study progress or results will be shared with participants in this study

29. Inclusion of Vulnerable Populations

29.1. As indicated under the Inclusion/Exclusion criteria (Section 4), the study staff will invite participation of persons found eligible by trained study personnel through standardized methods.

29.1.1. **Children** may not participate in this study.

29.1.2. **Pregnant women** – This research involves no more than minimal risk to the pregnant woman and fetus. No invasive procedures will be performed on the women or fetus.

29.1.3. **Prisoners** may not participate in this study.

29.2. For participants who may be vulnerable to coercion or undue influence, such as those with lower educational attainment and fewer economic resources, we will include the following safeguard to protect their rights and welfare.

29.2.1. The participants will be informed (verbally and as written in the consent form) that their involvement in the study is voluntary, and that they may choose not to participate. The participants will also be informed that they may also withdraw from the study at any time. Further, they will be informed that their decision to participate or not will have no impact upon the care they receive at the IHS, UNM Hospital or its Cancer Center.

29.2.2. The study staff personnel consenting the participants will assure that they have an understanding of the study. To enhance understanding, the coordinator will use methods such as appropriate feedback, multiple methods to convey study information. In addition, we have designed the consent form with an emphasis on simplicity, brevity, and plain language—elements documented to enhance understanding of consent information.

29.2.3. To ensure that the participants have understood information presented in the consent form, the study staff personnel will request the participants to teach-back the "learned" information. If the participants understood the consent information, they will be able to teach-back the information accurately; if not, the coordinator will explain the consent information once again.

30. Community-Based Participatory Research

a. The proposed project utilizes the community based participatory (CBPR) approach in all phases of the research. The CBPR approach effectively addresses mistrust of research and researchers through establishing a non-hierarchical partnership model. CBPR is used successfully to address a variety of health priorities and is a necessary research methodology with AIs. We will constitute an Advisory Panel comprising stakeholders representing Zuni community members and Community Health representatives (CHRs), cancer survivors, IHS healthcare providers, and researchers. The Panel will actively participate in the research, including finalization of the study aims, research design and approach, recruitment strategies, development of data collection instruments, and constituency checking of data inferences. We will (1) build on the various stakeholders' strengths, and integrate our respective knowledge and expertise and (2) support an inter-dependent partnership, with a long-term commitment for mutually beneficial co-learning and capacity enhancement. The Panel will comprise nine members and will meet every six months or more often if necessitated. Panel members will receive a $100 merchandise card for their participation and contributions. The project's PI, Dr. Mishra, has for over 20 years conducted community based participatory and community engaged research with socio-economically and racially/ethnically diverse and hard-to-reach populations including recent immigrants, migrant farmworkers, Hispanics, African-Americans, and indigenous American Samoans.

31. Research Involving American Indian/Native Populations

31.1. The research involves American Indian population residing in the Zuni Pueblo. The Zuni tribal leaders have identified health equity and reduction of cancer health disparities as a tribal priority. Moreover, the tribal leaders are fully supportive of the research project (see Letter of Support)

32. Transnational Research

N/A – this study does not involve transnational research in any form.

33. Drugs or Devices

N/A – this study is behavioral and does not involve testing of drugs or devices.

REFERENCES

1. Indian Health Service. *Quality of IHS Healthcare: Performance Measures.* Washington, DC: Indian Health Service. Available at: https://www.ihs.gov/crs/includes/themes/newihstheme/display_objects/documents/gpra/2016_GPRAResults_CRS.pdf. Accessed on September 21, 2017.
2. New Mexico Department of Health. *Health Indicator Report of Cancer Screening--Colorectal Cancer Screening.* Santa Fe, NM: New Mexico Department of Health, Indicator-Based Information System for Public Health. Available at: https://ibis.health.state.nm.us/indicator/view/CancerScrColoRec.Age50-75.RacEth.html. Accessed on September 22, 2017.
3. New Mexico Department of Health. *Health Indicator Report of Cancer Screening--Pap Test.* Santa Fe, NM: New Mexico Department of Health, Indicator-Based Information System for Public Health. Available at: https://ibis.health.state.nm.us/indicator/view/CancerScrPap.Age21-65.RacEth.html. Accessed on September 22, 2017.
4. New Mexico Department of Health. *Health Indicator Report of Cancer Screening--Mammography.* Santa Fe, NM: New Mexico Department of Health, Indicator-Based Information System for Public Health. Available at: https://ibis.health.state.nm.us/indicator/view/CancerScrMammo.RacEth.html. Accessed on September 22, 2017.
5. White MC, Espey DK, Swan J, Wiggins CL, Eheman C, Kaur JS. Disparities in cancer mortality and incidence among American Indians and Alaska Natives in the United States. *American journal of public health.* Jun 2014;104 Suppl 3:S377-387.
6. New Mexico Tumor Registry. *Cancer in New Mexico.* Albuquerque, NM: New Mexico Tumor Registry. Available at: http://nmtrweb.unm.edu/statistics/index.html. Accessed on September 21, 2017.
7. New Mexico Tumor Registry. *Opportunities for Cancer Control: An overview of screen-detectable and tobacco-related cancer in New Mexico.* Albuquerque, New Mexico: New Mexico Tumor Registry, 2013. Available at: http://nmtrweb.unm.edu/_pdf/OpportunitiesForCancerControl.pdf. Accessed on September 21, 2017.
8. Warne D, Kaur J, Perdue D. American Indian/Alaska Native cancer policy: systemic approaches to reducing cancer disparities. *Journal of cancer education : the official journal of the American Association for Cancer Education.* Apr 2012;27 Suppl 1:S18-23.
9. Pandhi N, Guadagnolo BA, Kanekar S, Petereit DG, Smith MA. Cancer screening in Native Americans from the Northern Plains. *American journal of preventive medicine.* Apr 2010;38(4):389-395.
10. Daley CM, James AS, Filippi M, et al. American Indian Community Leader and Provider Views of Needs and Barriers to Colorectal Cancer Screening. *Journal of health disparities research and practice.* 2012;5(2).
11. Filippi MK, James AS, Brokenleg S, et al. Views, barriers, and suggestions for colorectal cancer screening among american Indian women older than 50 years in the midwest. *Journal of primary care & community health.* Jul 1 2013;4(3):160-166.
12. James AS, Filippi MK, Pacheco CM, et al. Barriers to colorectal cancer screening among american Indian men aged 50 or older, kansas and missouri, 2006-2008. *Preventing chronic disease.* 2013;10:E170.
13. Schumacher MC, Slattery ML, Lanier AP, et al. Prevalence and predictors of cancer screening among American Indian and Alaska native people: the EARTH study. *Cancer causes & control : CCC.* Sep 2008;19(7):725-737.
14. Daley CM, Filippi M, James AS, et al. American Indian community leader and provider views of needs and barriers to mammography. *Journal of community health.* Apr 2012;37(2):307-315.
15. Daley CM, Kraemer-Diaz A, James AS, et al. Breast cancer screening beliefs and behaviors among American Indian women in Kansas and Missouri: a qualitative inquiry. *Journal of cancer education : the official journal of the American Association for Cancer Education.* Apr 2012;27(1 Suppl):S32-40.

16. Filippi MK, Ndikum-Moffor F, Braiuca SL, et al. Breast cancer screening perceptions among American Indian women under age 40. *Journal of cancer education : the official journal of the American Association for Cancer Education.* Sep 2013;28(3):535-540.
17. Giuliano A, Papenfuss M, de Guernsey de Zapien J, Tilousi S, Nuvayestewa L. Breast cancer screening among southwest American Indian women living on-reservation. *Preventive medicine.* Jan-Feb 1998;27(1):135-143.
18. Lin Y, Mousseau R. Barriers of female breast, colorectal, and cervical cancer screening among American Indians--where to intervene? *AIMS Public Health.* 2016;3(4):891-906.
19. Israel BA, Schulz AJ, Parker EA, Becker AB. Review of community-based research: assessing partnership approaches to improve public health. *Annual review of public health.* 1998;19:173-202.
20. Minkler M, Wallerstein N, eds. *Community-Based Participatory Research for Health: From Process to Outcomes.* San Francisco, CA: Jossey-Bass; 2008.
21. Hoffman RM, Sussman AL, Getrich CM, et al. Attitudes and Beliefs of Primary Care Providers in New Mexico About Lung Cancer Screening Using Low-Dose Computed Tomography. *Preventing chronic disease.* Jul 09 2015;12:E108.
22. Mishra SI, Bastani R, Crespi CM, Chang LC, Luce PH, Baquet CR. Results of a randomized trial to increase mammogram usage among Samoan women. *Cancer epidemiology, biomarkers & prevention : a publication of the American Association for Cancer Research, cosponsored by the American Society of Preventive Oncology.* Dec 2007;16(12):2594-2604.
23. Mishra SI, Chavez LR, Magana JR, Nava P, Burciaga Valdez R, Hubbell FA. Improving breast cancer control among Latinas: evaluation of a theory-based educational program. *Health education & behavior : the official publication of the Society for Public Health Education.* Oct 1998;25(5):653-670.
24. Mishra SI, Sussman AL, Murrietta AM, et al. Patient Perspectives on Low-Dose Computed Tomography for Lung Cancer Screening, New Mexico, 2014. *Preventing chronic disease.* Aug 18 2016;13:E108.
25. Bastani R, Gallardo NV, Maxwell A. Barriers to colorectal cancer screening among ethnically diverse high and average risk individuals. *Journal of Psychosocial Oncology.* 2001;19:65-84.
26. Bastani R, Glenn BA, Taylor VM, et al. Integrating theory into community interventions to reduce liver cancer disparities: The Health Behavior Framework. *Preventive medicine.* Jan-Feb 2010;50(1-2):63-67.
27. Bastani R, Maxwell AE, Bradford C, Das IP, Yan KX. Tailored risk notification for women with a family history of breast cancer. *Preventive medicine.* Nov 1999;29(5):355-364.
28. National Cancer Institute. *Theory at a Glance: A Guide for Health Promotion Practice.* Washington, DC: U.S. Department of Health and Human Services, National Institutes of Health; 2012.
29. Mishra SI, DeForge B, Barnet B, Ntiri S, Grant L. Social determinants of breast cancer screening in urban primary care practices: a community-engaged formative study. *Women's health issues : official publication of the Jacobs Institute of Women's Health.* Sep 2012;22(5):e429-438.
30. Mishra SI, Luce PH, Hubbell FA. Breast cancer screening among American Samoan women. *Preventive medicine.* Jul 2001;33(1):9-17.
31. Mishra SI, Luce-Aoelua PH, Hubbell FA. Predictors of papanicolaou smear use among american samoan women. *Journal of general internal medicine.* May 2001;16(5):320-324.
32. U.S. Census Bureau. Zuni Pueblo CDP, New Mexico. Available at: https://factfinder.census.gov/faces/nav/jsf/pages/community_facts.xhtml?src=bkmk. Accessed on November 30, 2017. 2017.
33. Burhansstipanov L, Christopher S, Schumacher SA. Lessons learned from community-based participatory research in Indian country. *Cancer control : journal of the Moffitt Cancer Center.* Nov 2005;12 Suppl 2:70-76.
34. Kaur JS, Dignan M, Burhansstipanov L, Baukol P, Claus C. The "Spirit of Eagles" legacy. *Cancer.* Oct 15 2006;107(8 Suppl):1987-1994.
35. Noe TD, Manson SM, Croy C, McGough H, Henderson JA, Buchwald DS. The influence of community-based participatory research principles on the likelihood of participation in health research in American Indian communities. *Ethnicity & disease.* Winter 2007;17(1 Suppl 1):S6-14.
36. Strickland CJ. Challenges in community-based participatory research implementation: experiences in cancer prevention with Pacific Northwest American Indian tribes. *Cancer control : journal of the Moffitt Cancer Center.* Jul 2006;13(3):230-236.

37. Freire P. Cultural action and conscientization. *Harvard Education Review.* 1977;40:452-477.
38. Krueger RA, Casey MA. *Focus Groups: A Practical Guide for Applied Research (4th Edition).* Thousand Oaks, CA: Sage Publciations, Inc; 2009.
39. U.S. Preventive Services Task Force. *Final Recommendation Statement: Breast Cancer: Screening.* Rockville, MD: U.S. Preventive Services Task Force, November 2016. Available at: https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/breast-cancer-screening1. Accessed on September 22, 2017.
40. U.S. Preventive Services Task Force. *Final Update Summary: Colorectal Cancer: Screening.* Rockville, MD: U.S. Preventive Services Task Force, June 2016. Available at: https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/colorectal-cancer-screening2. Accessed on September 22, 2017.
41. U.S. Preventive Services Task Force. *Final Update Summary: Cervical Cancer: Screening.* Rockville, MD: U.S. Preventive Services Task Force, June 2016. Available at: https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/cervical-cancer-screening. Accessed on September 22, 2017.
42. Creswell JW. *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches.* Thousand Oaks, CA: Sage Publications, Inc; 2014.

Checklist Section

This section contains checklists to provide information on a variety of topics that require special determinations by the IRB. Please complete all checklists relevant to your research.

I. Waivers or Alterations of Consent, Assent, and HIPAA Authorization

A. Partial Waiver of Consent for Screening/Recruitment

Complete this checklist if you are requesting a partial waiver of consent so that you can review private information to identify potential subjects and/or determine eligibility prior to approaching potential subjects for consent or parental permission.

1. Describe the data source that you need to review (e.g., medical records):

   We will collect PHI (names, address, and phone number) from participants interested and eligible for the study. We will use the PHI solely to contact participants so as to schedule them for data collection activities. The database containing the PHI information will be kept in a password protected file separate from the study database. Access to this file will be limited to the PI and research staff responsible for contacting and scheduling participants for data collection activities.

2. Describe the purpose for the review (e.g., screening):

   We will collect the PHI so as to contact participants for the respective data collection activities, i.e., focus groups, interviews, and surveys.

3. Describe who will conducting the reviews (e.g., investigators, research staff):

   The PHI information will be collected by research staff.

4. Do all persons who will be conducting the reviews already have permitted access to the data source?

   ☒ Yes

   ☐ No. Explain:

5. Verify that each of the following are true or provide an alternate justification for the underlined regulatory criteria:

   a) The activity involves no more than minimal risk to the subjects because the records review itself is non-invasive and the results of the records review will not be used for any purposes other than those described above.

      ☒ True

      ☐ Other justification:

b) The waiver or alteration will not adversely affect the rights and welfare of the subjects because eligible subjects will be approached for consent to participate in the research and are free to decline. Further, the information accessed during the records review will not be disclosed to anyone without a legitimate purpose (e.g., verification of eligibility).

☒ True

☐ Other justification:

c) The research could not practicably be carried out without the waiver or alteration because there is no other reasonably efficient and effective way to identify who to approach for possible participation in the research.

☒ True

☐ Other justification:

d) Whenever appropriate, potentially eligible subjects will be presented with information about the research and asked to consider participation. *(Regulatory criteria: Whenever appropriate, the subjects will be provided with additional pertinent information after participation.)*

☒ True

☐ Other justification:

Partial Waiver of HIPAA Authorization for Screening/Recruitment
Complete the following additional questions/attestations if the records you will review to identify potential subjects and/or determine eligibility include Protected Health Information (PHI).

6. Will you be recording any PHI when conducting the records review to identify potential subjects and/or determine eligibility?

   ☒ Yes. Describe: *We will collect PHI (name and contact information) from participants who are interested and eligible for the study. We will collect this information solely for scheduling purposes.*

   ☐ No

7. If you answered "Yes" to question 6 above, please describe when you will destroy identifiers (must be the earliest opportunity consistent with the conduct of the research) or provide justification for why they must be retained:

   We will destroy PHI of participants as soon as we have scheduled and completed collecting data from them.

8. The PHI accessed or recorded for identification/screening purposes will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

   ☒ True

   ☐ False

B. Waiver of Documentation of Consent

Complete this checklist if you intend to obtain consent verbally but will not be obtaining signatures from subjects on a consent form to document consent. Waivers of documentation of consent are commonly requested when using scripts, information sheets, or email or survey introductions to present the elements of consent instead of using a traditional consent form.

1. Are you requesting a waiver of documentation of consent for some or all subjects?

   ☒ All

   ☐ Some. Explain:

2. Provide justification for <u>one</u> of the following:

   a) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

   b) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

      The proposed project poses no greater than minimal risk to the participants. While we need information to contact and schedule participants initially. Upon completion of their participation (focus group attendance, interview, or survey) no PHI is needed and will not be kept. The project was originally granted a waiver of written consent. However, as per guidance from the Southwest Tribal IRB that it prefers researchers obtain written consent, at our last modification request to UNM HSC IRB, we had changed our consent letter by adding a signature line.

In an effort to mitigate the spread of COVID-19 we have now modified our research approach to conduct all activities (recruitment, eligibility determination, and data collection) over the phone, except for mailing the merchandise cards. Therefore, we are using a Consent Letter and not adding a line for the participant to sign her/his name. As part of the next modification request to the SWTIRB, we will communicate our rationale specific to the public health emergency as a reason for reverting to a Consent Letter.

3. Do you intend to provide subjects with a written statement regarding the research in lieu of a traditional consent form?

   ☒ Yes. Please attach a copy to your submission in Click. We will mail the Consent Letter if the participant requests a copy.

   ☐ No

C. Alteration of Consent

Complete this checklist if you intend to obtain consent but will be eliminating or altering one or more of the required elements of consent. Alterations of consent are commonly requested for research involving deception or for minimal risk research when an abbreviated consent is desired and one or more of the required element are not relevant to the research.

Note: FDA-regulated research is not eligible for an alteration of consent.

1. Which element(s) of consent do you wish to eliminate and why?

2. Which element(s) of consent do you wish to alter and why?

3. Provide justification for each of the following regulatory criteria:
   a) The research involves no more than minimal risk to the subjects:

   b) The waiver or alteration will not adversely affect the rights and welfare of the subjects:

   c) The research could not practicably be carried out without the waiver or alteration:

   d) Whenever appropriate, the subjects will be provided with additional pertinent information after participation:

D. Full Waiver of Consent/Parental Permission

Complete this checklist if you are requesting a full waiver of consent for all subjects or certain subject groups (e.g., retrospective cohort). Full waivers of consent are commonly requested when the research does not include any opportunity for interaction with subjects (e.g., chart review).

Note: FDA-regulated research is not eligible for a full waiver of consent using these criteria. If you believe that your FDA-regulated research may be eligible for a waiver under another mechanism, such as planned emergency research, contact the HRPO for assistance in determining what information to provide to the HRRC.

1. Are you requesting a waiver for some or all subjects?

   ☐ All

   ☐ Some. Explain:

2. Provide justification for each of the following regulatory criteria:

   a) The research involves no more than minimal risk to the subjects:

   b) The waiver or alteration will not adversely affect the rights and welfare of the subjects:

   c) The research could not practicably be carried out without the waiver or alteration:

   d) Whenever appropriate, the subjects will be provided with additional pertinent information after participation:

E. Full Waiver of Consent/Parental Permission (Public Benefit or Service Programs)

Complete this checklist if you are requesting a full waiver of consent for all subjects or certain subject groups (e.g., retrospective cohort) and the research involves the evaluation of a public benefit or service program.

1. Are you requesting a waiver for some or all subjects?

   ☐ All

   ☐ Some. Explain:

2. Provide justification for each of the following regulatory criteria:

    a) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs:

    b) The research could not practicably be carried out without the waiver or alteration.

F. Full Waiver of HIPAA Authorization

Complete this checklist if you are requesting a full waiver of the requirement to obtain HIPAA authorization for all subjects or certain subject groups (e.g., retrospective cohort). Full waivers of HIPAA authorization are commonly requested when the research does not include any opportunity for interaction with subjects (e.g., chart review).

1. Are you requesting a waiver of authorization for some or all subjects?

    ☐ All

    ☐ Some. Explain:

2. Describe your plan to protect health information identifiers from improper use and disclosure:

3. Describe your plan to destroy identifiers at the earliest opportunity consistent with conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so):

4. Describe why the research could not practicably be conducted without the waiver or alteration:

5. The PHI accessed or recorded for identification/screening purposes will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

☐ True

☐ False

G. Other Waiver Types

If you are seeking another waiver type (e.g., Planned Emergency Research, Waiver of Parental Permission to Protect Child Participants, Enforcement Discretion for In Vitro Diagnostics, etc. contact the HRPO office for assistance in determining what information to submit for the HRRC's consideration.

II. Vulnerable Populations

A. Children

Complete this checklist if the subject population will include children.

1. Select the category of research that you believe this research falls within and provide justification for any associated criteria. If there are different assessments for different groups of children or arms (e.g., placebo vs. drug), include a memo to provide an assessment for each group.

   ☐ Research not involving greater than minimal risk. *(Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)*

   ☐ Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

   Provide justification for each of the following criteria:

   (1) The risk is justified by the anticipated benefit to the subjects:

   (2) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches:

   ☐ Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

   Provide justification for each of the following criteria:

   (1) The risk represents a minor increase over minimal risk:

(2) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations:

(3) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition