

COVER LETTER

Official Title of Study: Nenunkumbi/Edahiyedo ("We Are Here Now"): A Mult-level, Multi-component Sexual and Reproductive Health Intervention for American Indian Youth

NCT number: 03694418.

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This document contains the following: 1) study summary; 2) study protocol; 3) analysis plan; 4) study intervention administration of data collection; 5) selection and enrollment of participants; 6) human subjects; 7) data safety monitoring plan; 8) revision history; and 9) appendices.

Institutional Review Board Approval was received from Montana State University on February 5, 2018 and from the Fort Peck Tribes on October 29, 2018. These IRB approvals as well as subsequent IRB modification requests due to the COVID 19 pandemic are in the appendices. Updated IRB approvals from Montana State University (11.06.20- 5-year renewal timeline) and the Fort Peck Tribes (11.02.23 - yearly renewal timeline) were included in the appendices on 9.25.24.

Nenunkumbi/Edahiyedo ("We Are Here Now"): A Mult-level, Multi-component Sexual and Reproductive Health Intervention for American Indian Youth

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Nenunkumbi/Edahiyedo ("We Are Here Now") is an equitable collaborative community-academic partnership grounded in trust, respect, mutual understanding and a commitment to improving the lives of young people and their families on the Fort Peck Indian Reservation.

Nenunkumbi/Edahiyedo ("We Are Here Now") is implemented by: Fort Peck Community College, the Fort Peck Tribes Language and Cultural Department, the Fort Peck Tribal Health Department, the school districts of Frazer, Wolf Point, Poplar, Brockton and Culbertson and Montana State University.

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SECTION 1: STUDY SUMMARY

American Indian (AI) communities in the United States (US) are disproportionately affected by sexual and reproductive health disparities, compared to other populations, placing current and future generations of AI societies in jeopardy. Our study, "Nen OnkUmbi/EdaHiYedo (*NIE* - "We are Here Now")", utilizes a culturally tailored ecological intervention in which the prevention of sexual-risk behaviors among AI youth that lead to STIs, HIV, HCV, and teen pregnancy are addressed. *N/E* takes place on the Fort Peck Reservation in northeastern Montana. *N/E* is a community-based participatory research sexual and reproductive health (SRH) intervention, constructed on Ecological Systems Theory. Based on Fort Peck tribal members' desire to implement a holistic SRH intervention for the tribes' youth, *N/E* includes: 1) A school-based SRH curriculum called Native Stand, designed to address individual-level factors that lead to risky behaviors; 2) a family-level curriculum called Native Voices, tailored to increase communication between adult family members and youth about SRH topics; 3) a cultural mentoring component at the community-level that pairs AI youth with adults and elders to discuss traditional AI beliefs and practices about SRH; and 4) a systems-level strategy to activate a multi-sectoral network of local youth servicing organizations to coordinate SRH services. The overarching aim of this proposal is to refine and tailor the components of *N/E* and evaluate its efficacy. *N/E* is a 5-year study involving 456 15- to 18-year-old AI youth and their parent/legal guardian.

SECTION 2: STUDY PROTOCOL

2.1 Study Team Roster. *NIE's* tribal community and academic study team combines Indigenous expertise in traditional knowledge, contemporary reservation culture, and local tribal resources and skills with Westernized research experience in SRH interventions among Indigenous populations and qualitative and quantitative research methodologies. The study team members are listed below.

- **Elizabeth Rink**, Ph.D., MSW, at Montana State University (MSU) is the principal investigator (PI) for *NIE*. Dr. Rink will be responsible for the overall research and fiscal administration, implementation, and evaluation of *NIE*.
Email: elizabeth.rink@montana.edu
- **Paula FireMoon** (Sioux), M.A., is *NIE's* Fort Peck-based Project Director. Ms. FireMoon will oversee community participation, including implementation of *NIE*, and coordination of *NIE's* research activities with tribal schools, health care facilities, and other youth-servicing agencies on the Fort Peck Reservation.
Email: PFiremoon@fpcc.edu
- **Ramey Growing Thunder** (Sioux/Navajo), M.Ed., is director of the Fort Peck Tribes' Language and Culture Department. Mrs. Growing Thunder will lead the implementation of *NIE's* cultural mentoring program.
Email: rgrowingthunder@gmail.com
- **Adriann Ricker** (Assiniboine), MPH, CHES, is associate director of the Fort Peck Tribes' Health Promotion and Disease Prevention Program. Ms. Ricker will increase coordination among, and access to, SRH services for AI youth in schools, health care facilities, and youth-servicing agencies at Fort Peck.
Email: adricker@gmail.com
- **Community Advisory Board** (CAB) that includes five tribal members. CAB members are: Ingrid FireMoon - Email: IFiremoon@fortpecktribes.net, Bruce Bauer- Email: bwbauer@yahoo.com, Olivia Johnson - Email: ojohnson@brockton.k12.mt.us; Martel Reum - Email: MReum@fpcc.edu; and Alexandria Herrald - Email: alexandria.herrald26@gmail.com.
- **Julie Baldwin** (Cherokee), Ph.D., director of The Center for Health Equity Research at Northern Arizona University, with over 20 years of research expertise in the design, implementation, and

evaluation of HIV and substance abuse prevention interventions for AI youth is the study's Co-Investigator and senior research mentor to Dr. Rink.

Email: Julie.Baldwin@nau.edu.

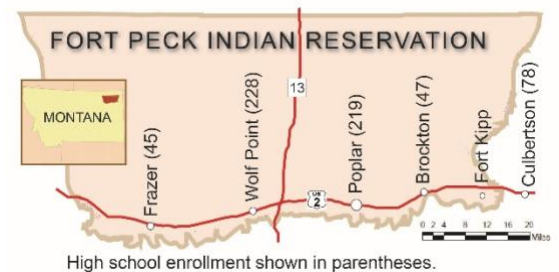
- **Mike Anastario**, Ph.D., is Co-Investigator and statistician for the study.
Email: manastar@fiu.edu.
- **Rachel Hallum-Montes**, Ph.D., an independent contractor who has worked on a variety of national teen pregnancy-prevention studies with the CDC will consult on the assessment of the coordination and implementation of SRH services for AI youth.
Email: rhallum.montes@gmail.com.
- **Genevieve Cox**, Ph.D., NIE's MSU-based research program manager.
Email: genevieve.cox@montana.edu.

2.2 Study Sites. NIE is implemented on the Fort Peck Reservation in Northeastern Montana. Fort Peck is located in a Northern Plains frontier environment and spans 2.1 million acres. It borders the 47½ parallel to the north Uust south of the border with Canada), with Big Muddy Creek to the east, the Missouri River to the south, and Big Porcupine Creek to the west. Approximately 8,000 enrolled tribal members, predominately from the Assiniboine and Sioux Nations, live on the reservation. The Assiniboine and Sioux are descendants of the Nakada, Nakata, Nakona, Lakota, and Dakota Nations. The Assiniboine comprise Wadopana (Canoe Paddlers Who Live on the Prairie) and Hudashana (Red Bottom) bands, and the Sioux comprise Sisseton/Wahpetons, the Yanktonais, and the Teton Hunkpapa bands. NIE will be implemented in the communities of Frazer, Wolf Point, Poplar, Brockton, and Culbertson. These 5 communities have public high schools that serve AI students. Frazer, Wolf Point, Poplar, and Brockton are on the reservation, and Culbertson is a border town on the east end of the reservation that AI youth from the reservation community of Fort Kipp attend (See Figure 1 for map of reservation and high schools).

Collaborating entities in NIE are:

- **Montana State University**, 318 Herrick Hall, Bozeman, MT. 59715, phone: 406.994.3833, Fax: 406.994.2013
- **Fort Peck Community College**, PO Box 398 Poplar, MT. 59255, phone: (406) 768-6300, Fax: 768.6301
- **The Fort Peck Tribes Language and Cultural Department**, 603 Court Avenue, PO Box 1027, Poplar, MT. 59255, phone: 406.768.3520, Fax: 406.768.3531.
- **The Fort Peck Tribal Health Department**, 107 H Street East, PO Box 1027, Poplar, MT. 59255, Phone: 406. 653.1191, Fax: 406. 768.5780.
- **Frazer Public School**, 325 6th Street, Frazer, MT. 59225, Phone: 406.695.2241, Fax: 406. 695.2243.
- **Wolf Point School District**, 213 6th Ave. South, Wolf Point, MT. 59201, Phone: 406.653.2361, Fax: 406. 653.3405.
- **Poplar School District**, 400 4th Avenue West, Poplar, MT. 59255, Phone: 406.768.6600, Fax: 406.768.6800.
- **Brockton School District**, 215 North 5th Street, Brockton, MT. 59213, Phone: 406.768.3311, Fax: 406. 786.3377.
- **Culbertson School**, 423 1st Avenue West, P.O. Box 459, Culbertson, MT. 59218, Phone:

Figure 1. Study sites on or near the Fort Peck Reservation.



406.787.6241, Fax: 406.787.62

2.3 RESEARCH DESIGN OVERVIEW

2.3.1 Study Title. Nenunkumbi/Edahiyedo ("We Are Here Now"): A Multi-level, Multi-component Sexual and Reproductive Health Intervention for American Indian Youth

2.3.2 Study Aims.

- **AIM 1** begins with a year of formative work to refine and tailor the components of N/E. Our community advisory board and the Fort Peck-based and MSU-based research team will design culturally appropriate adaptations for N/E's 4 levels.
- **AIM 2** tests the efficacy of N/E using a cluster-randomized stepped-wedge design (SWD), in which the 5 high schools that Fort Peck youth attend are randomized into the intervention 1 at a time. N/E's primary outcome is increased condom use during sexual intercourse. Secondary outcomes are delayed onset of sexual intercourse, number of sex partners, frequency of sexual intercourse, pregnancy history, consistent use of birth control during sexual intercourse, and whether alcohol and/or other drugs are used during sexual intercourse. Tertiary outcomes are increased parent/legal guardian-child communication about SRH topics, increased understanding of cultural values related to traditional AI beliefs regarding SRH, and increased use of SRH services. Quantitative data collection includes: student surveys at baseline, 3, 9 and 12 months; parent/legal guardian surveys at baseline, 9 and 12 months. Qualitative data collection includes SRH service provider discussion groups at baseline and thereafter once a year over the 5-year study, with logs to track coordination and implementation at baseline and 3, 6, 9 and 12 months.
- **AIM 3** will evaluate the fidelity and acceptability of N/E with focus groups, activity logs, and staff meeting notes and staff field notes.

Our **long-term goal** is to produce a toolkit, including curriculum manuals, an SRH cultural mentoring program, and specific systems-level actions suitable for replication in other tribal communities. The **public health impact** is the prevention of STIs, HIV, HCV, and teen pregnancies in AI youth resulting in reduced sexual and reproductive health disparities and improved health in AI families and communities.

2.3.3 Design Overview. *NIE* is a community-based participatory research (CBPR) multi-level, multi-component sexual and reproductive health (SRH) intervention, constructed on Ecological Systems Theory. *NIE* is based on Fort Peck tribal members' desire to implement a holistic SRH intervention for AI youth. *NIE* includes: 1) A school-based SRH curriculum called *Native Stand*, designed to address **individual-level** factors that lead to sexual risk behaviors; 2) a **family-level** curriculum called *Native Voices*, tailored to increase communication between adult family members and youth about SRH topics; 3) a cultural mentoring component at the **community level** that pairs AI youth with adults and elders to discuss traditional AI beliefs and practices about SRH; and 4) a mobilizing strategy to activate a multi-sectoral network of youth-servicing organizations at the **systems level** in Fort Peck to coordinate SRH services for AI youth. The overarching aim of this study is to refine, tailor, and finalize the components of *NIE* and evaluate its efficacy. We will use a cluster-randomized stepped-wedge design (SWD), in which 5 schools that AI youth from Fort Peck attend are the clusters to be randomized into the intervention 1 at a time, with all schools eventually being randomized to the intervention. The 5 schools are located in separate communities, mitigating the potential for cross-contamination. *NIE* is a 5-year study involving 456 15- to 18-year-old AI youth.

2.3.4 Intervention Design. *NIE* is a 5-year CBPR ecological intervention for 456 15- to 18-year-old AI youth living on the Fort Peck Reservation. *Nen OnkUmbilEdaHiYedo* ("We Are Here Now") derives from the Assiniboine (*Nen OnkUmbt*) and Sioux (*EdaHiYedo*) names for their traditional coming-of-age ceremonies, when, at the age of 15 and over, young tribal members are believed to be ready for integrated education and training on sex, what it means to be a man or a woman, relationships, having children, and being a parent. *NIE* is guided by a 5-member CAB. The primary institutional partners responsible for the implementation of *NIE* are Fort Peck Community College (FPCC), the Fort Peck Tribes Language and Culture Program, the Fort Peck Tribal Health Department (Epi Team)¹, and MSU.

NIE will be implemented simultaneously over the 9-month school year (Table 1). Components include: 1) **Individual Level.** *Native Stand* is a school-based, 27-module STI-, HIV-, and teen pregnancy-prevention curriculum, originally developed for rural white youth and adapted in 2008 as a stand-alone SRH curriculum for AI youth. For *NIE*, an adaptation of *Native Stand* will be implemented in the study's 5 high schools to educate AI youth on sexual risk behavior prevention strategies. The tailoring of *Native Stand* will reduce its 27 modules to 18 modules and will include specific community-relevant traditional and contemporary cultural lesson plans. *Native Stand* will be integrated into each of the 5 schools' established curriculum and will be delivered by the *NIE* School Coordinator in a classroom setting as part of the students' regular class schedule. 2) **Family Level.** *Native Voices* is a video-based HIV/STI-prevention intervention designed for AI youth to address condom use, negotiation skills, group discussion, and role playing. *Native Voices* will be adapted from 1 module into 4 modules to involve parents/legal guardians, as recommended by the CDC. Our adaptation of *Native Voices* involves students with one of their parents/legal guardians to promote parent/legal guardian/youth discussions about preventing STIs, HIV, HCV, and teen pregnancy. The *NIE* School Coordinator will present *Native Voices* to groups of students and their parents/legal guardians at the study's high schools for 2 hours in the evening. 3) **Community Level.** The third level of *NIE* is a cultural mentoring component that pairs AI youth with older adults and elders to discuss traditional AI beliefs and practices about reproductive health. The mentoring program is based on Assiniboine and Sioux traditional knowledge and the National Mentoring Partnership standards for mentoring. The mentoring program was designed specifically for Fort Peck youth by the Fort Peck Tribes' Language and Culture Department and has been in existence for 5 years. *NIE* integrates this cultural mentoring program into *NIE*'s overall framework with an emphasis on addressing traditional topics related to SRH, such as overall information on cultural beliefs, values, and ceremonies, and more specific information on cultural beliefs and values regarding sex, having children, parenting, and relationships. Our cultural mentoring program will include older male and female tribal members who will be paired with the youth by gender and tribal affiliation. AI youth will meet one-on-one with their mentors each month and also monthly in mentor-mentee small groups. Depending on the purpose of the cultural mentoring sessions, the sessions will take place at either the study's high schools, the Fort Peck Language and Culture Department's main office in Poplar, community centers on the reservation, or at the Buffalo Ranch. Ramey Growing Thunder will oversee the implementation of the cultural mentoring program. 4) **Systems Level.** The fourth level of *NIE* mobilizes the existing Epi Team to enhance the coordination and implementation of SRH services at Fort Peck. The members of the Epi Team will utilize the recommendations in the CDC's *Contraceptive and Reproductive Health Services for Teens: Evidence-based Clinical Best Practices Guide* to enhance the coordination and implementation of SRH services for AI youth. This enhancement process will take place during the Epi Team's monthly meetings at the Fort Peck Tribal Headquarters in Poplar by developing a coordination and monitoring plan that can be tracked over time to address the barriers, facilitators, and solutions to increase access to SRH

¹ Fort Peck Tribal Epidemiology Team (Epi Team), which is a local committee that has been in existence for 15 years to monitor diseases on the reservation and the health status of tribal members. The Epi Team is comprised of the Fort Peck Tribal Health Department; the Indian Health Service (Poplar Service Unit and Wolf Point Service Unit); the Roosevelt County Health Department; school nurses from the Fort Peck Health Promotion and Disease Prevention Program; the high schools of Frazer, Wolf Point, Poplar, Brockton, and Culbertson; and the Fort Peck Tribal Executive Board.

services for AI youth at Fort Peck. Dr. Rink, Ms. FireMoon, Ms. Ricker and Dr. Cox will attend the Epi Team's monthly meetings to work in partnership to implement *NIE's* systems-level component.

Table 1. Overview of *N/E's* 9-month multi-level, multi-component intervention plan.

INDIVIDUAL	FAMILY	COMMUNITY	SYSTEMS
Native Stand (NS): 18-session school-based curriculum delivered twice a month over 9 months in <i>N/E's</i> 5 participating schools. NS will be integrated into the schools' existing class schedules.	Native Voices (NV): 4 sessions delivered once every other month to students and parents/legal guardians after school hours at <i>N/E's</i> 5 participating schools.	Cultural Mentoring Program (CMP): 9 mentoring sessions delivered twice a month over 9 months that include one group activity with CMP mentors and mentees and one 1:1 meeting. CMP activities will take place at varying locations on the Reservation depending on the activity.	SRH Services: Monthly meetings over 12 months with Epi Team at the Fort Peck Tribes Headquarters offices in Poplar, Montana.
NS 1: Introduction to an overview of <i>N/E</i> and Native Stand	NV 1: Introduction to an overview of <i>N/E</i> and Native Voices	CMP 1: Assiniboine/Sioux kinship networks and concepts of family and genealogy	Epi Team meetings will take place monthly over 9 months to enhance coordination and implementation of SRH services for AI youth.
NS 2: Culture & Tradition – Part 1		CMP 2: Traditional male/female roles and cultural beliefs about healthy relationships	
NS 3: Culture & Tradition – Part 2			
NS 4: Healthy Relationships – Part 1			
NS 5: Healthy Relationships – Part 2	NV 2: Talking with youth about topics related to sex	CMP 3: Cultural beliefs about sex and how to make decisions about sex that integrate cultural values	
NS 6: Reproductive Health – Part 1		CMP 4: Cultural beliefs about parenting and the role of family	
NS 7: Reproductive Health – Part 2			
NS 8: Pregnancy & Parenting			
NS 9: Preventing Pregnancy	NV 3: Prevention of STIs, HIV/AIDS, and HCV	CMP 5: The role of ceremony in traditional Assiniboine/Sioux culture	
NS 10: Condoms & Birth Control		CMP 6: The role of sweat lodges in AI spirituality	
NS 11: Sexually Transmitted Diseases			
NS 12: HIV/AIDS & HCV			
NS 13: Drugs, Alcohol, & Sex	NV 4: Strategies for fostering healthy relationships in your child's intimate relationships	CMP 7: Honoring ceremonies in the lives of young men and women	
NS 14: Mental Health & Sex		CMP 8: Understanding the sacredness of the land	
NS 15: Negotiation & Refusal Skills			
NS 16: Decision-Making			
NS 17: Effective Communication	CMP 9: Buffalo Harvest		
NS 18: Putting It All Together			

2.3.5 Trial Design.

Our selection of an SWD to evaluate *NIE* is consistent with tribal members' desires that all 15- to 18-year-old AI youth receive the intervention. The SWD is a cluster-randomized trial, which involves random and sequential crossover of clusters from control to intervention until all clusters are exposed to the intervention.^{5 29} The first observation period corresponds to a baseline measurement observation, in which none of the clusters have been randomized to *NIE*. Clusters are randomized to *NIE* at subsequent steps until all clusters have

completed treatment. ***Following randomization of the schools to the intervention, there will be three waves of implementation: Wave 1 (1 school in 2019), Wave 2 (2 schools in 2019-2020), and Wave 3 (2 schools in 2020-2021).*** The 5 schools on the Fort Peck Reservation will be the clusters that are randomized to *NIE*. *NIE* will take approximately 40 weeks, or 3 quarters, to implement. The first observation period (Q4 of Year 2) provides baseline measurements for all respondents drawn from every cluster. The cluster is then surveyed at 3, 9, and 12 months for the students in the cluster once they have begun participation in the intervention, and at 9 and 12 months for the parents/legal guardians in the cluster once they have begun participation in the intervention. Following completion of the intervention across all clusters, we will conduct the quantitative analysis. The SWD allows us to control for the effect of time and ensure that the full AI population of schools at Fort Peck receives *NIE*. The systems-level component of *NIE* will be implemented reservation-wide rather than school-wide during Years 2 to 4 of *NIE* as the SWD is rolled out. The systems level component will be measured and analyzed qualitatively.

2.3.6 Trial Timeline. The timeline for *NIE* is: Year 1-Refine, tailor, and finalize the components of *NIE* with the CAB by reviewing our current quantitative and qualitative data from Fort Peck and by talking with elders

Figure 4. Trial design and timeline for implementing N/E relative to grant and sites/schools.

YEAR 1 (2018)				YEAR 2 (2019)				YEAR 3 (2020)				YEAR 4 (2021)				YEAR 5 (2022)						
Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4			
Refine and tailor components of N/E	Site 1	bsln		3mf		N/E 9mf		12mf												Analysis / Sustainability Planning	→	Publication and Dissemination
	Site 2	bsln				3mf		N/E 9mf		12mf												
	Site 3	bsln				3mf		N/E 9mf		12mf												
	Site 4	bsln								3mf		N/E 9mf		12mf								
	Site 5	bsln								3mf		N/E 9mf		12mf								
																						Cluster unexposed to N/E
																						Intervention cluster
																						Post-intervention cluster
																						bsln = baseline data collection; mf = 3, 9, or 12 months

	Cluster unexposed to N/E
	Intervention cluster
	Post-intervention cluster
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and community stakeholders. We will have monthly team meetings and quarterly CAB meetings. When necessary, we will meet with CAB members individually. We will also recruit, hire, and train staff in *Native Stand* and *Native Voices*; identify the cultural mentors; purchase all necessary materials and supplies; finalize research protocols and IRB approvals. Years 2, 3, and 4- Collect baseline data; Implement *NIE*; conduct quantitative and qualitative data collection; conduct ongoing fidelity and acceptability data collection; and continue monthly team meetings and quarterly CAB meetings. Year 5-Finish data collection; conduct data analysis; work with CAB on interpretation of data analysis; develop sustainability plan; develop intervention toolkit; and disseminate results to scientific, professional, and Fort Peck communities. See Appendices for *NIE* timeline.

2.3.7 Sample Size and Population. *NIE*'s sample size is 456 AI male and female youth ages 15 to 18 years old. The population of AI youth 15 to 18-year-old attending the five schools participating in the study is approximately 617.

2.3.8 Study Background and Rationale. Comprehensive national surveillance data on SRH among AIs is difficult to assess due to the underrepresentation of AIs in national surveys. The data on AI SRH in the United States that are available demonstrate that AIs are disproportionately affected by adverse conditions attributable to SRH, compared to other populations. AI youth report earlier onset of sexual intercourse than other adolescent populations in the U.S. The teen birth rate among AIs is 2 to 3 times higher than that among Caucasians. In addition, the rates of pre-term birth and low birth weight are much higher in AIs compared to Caucasians. STIs are up to 4.6 times higher for AI males and females compared to Caucasians, with young AI males having the highest chlamydia rates of any racial- and age-specific population in the U.S. As a result, AI females have higher rates of miscarriages and ectopic pregnancies than Caucasian females and are at risk for infertility. For AI males, STIs can lead to urethritis, epididymitis, and prostate cancer, which is higher in AI men than all other racial and ethnic males in the U.S. In addition, the costly and burdensome health consequences of AI youths' high STI rates include infection with HIV and HCV. The incidence of HIV in AI males and females is 30% higher than in Caucasian males and females, and in recent years AIs are the only racial and ethnic group in which the incidence of HIV continues to rise. Furthermore, of all population subgroups in the U.S., the incidence of HCV is highest in AIs. At present no extant multi-level, multi-component intervention has been shown to be efficacious in addressing SRH among AI youth. The majority of AI interventions appearing in the peer-reviewed literature instead focus on alcohol and substance use reduction. Thus, a critical need exists to address the SRH disparities among AI youth, which place current and future generations of AI societies in jeopardy.

The literature related to SRH among AI youth identifies poverty, isolation, alcohol and other drug use, physical and sexual victimization, and lack of comprehensive and coordinated SRH education and clinical services as factors that influence unintended pregnancies and STIs. Evidence also suggests that ambivalence toward sex, social pressures, depression, anxiety, and experiences of historical trauma and loss influences sexual risk behavior among AIs. Mistrust of research and researchers continues in AI communities due to a legacy of neglect and betrayal by the U.S. government and by researchers from outside their communities. This mistrust impedes the cooperation between tribal communities and academics to design, implement, and evaluate effective interventions to address SRH disparities among AI youth.

The complex factors that influence sexual risk behaviors among AI youth warrant novel AI community-specific interventions. Previous research with AI youth on SRH has lacked an ecological design and implementation, and it has neither addressed nor leveraged the interconnectedness of the individual, family, community, and larger systems in preventing STIs, HIV, HCV, and teen pregnancy. Furthermore, CBPR, which has become an established methodological framework for partnering with AI communities to conduct research, has been sparsely applied to understanding and addressing Indigenous SRH. CBPR has the potential to facilitate the

implementation and evaluation of an ecological intervention in AI communities, particularly given its amenability to multi-sectoral and multi-level stakeholder involvement in the research process.

SECTION 3: ANALYSIS PLAN

3.1.1 Power analysis. Sample size requirements were calculated taking into account a unique design effect for the SWD,² such that $N_{sw} = Nu \times DE_{sw}$ (where Nu is the total number of students needed to detect the treatment effect with a power of 80% and a significance level of 0.05, uncorrected for cluster and repeated measurements). The design effect was calculated as:

$$DE_{sw} = \frac{1 + \rho(ktn + bn - 1)}{1 + \rho\left(\frac{1}{2}ktn + bn - 1\right)} \times \frac{3(1 - \rho)}{2t\left(k - \frac{1}{k}\right)}$$

where k is the number of steps, n is the expected number of students per cluster, b is the number of baseline measurements, t is the number of measurements after each step, and ρ is the intra-class correlation coefficient, estimated to be 0.016 based on findings reported by Kaufman et al.³ With an ρ of 0.05, power of 0.8, $Nu = 292$, $DE_{sw} = 1.3273$, and the expectation of 15% attrition during the study, a sample size of 456 will allow the detection of a 0.14 increase in the proportion of condom use relative to the frequency of sexual intercourse from baseline to the 12-month observation period hypothesized under Aim 2.

3.1.2 Missing data. Attrition is likely to covary with truancy, suggesting a missing data mechanism that is not missing at random (NMAR). To address this, a dropout variable D_i will be developed for each individual across the 4 observation periods, where $D_i = k$ for dropout between the $(k-1)$ th and k th occasion. A model of the probability of dropout, where

$\log \left\{ \frac{\Pr(D_i = k | D_i \geq k, Y_{i1}, \dots, Y_{ik})}{\Pr(D_i > k | D_i > k, Y_{i1}, \dots, Y_{ik})} \right\} = \theta_1 + \theta_2 Y_{ik-1} + \theta_3 Y_{ik}$ presumes that $\theta_3 \neq 0$ for the NMAR mechanism. Missing data will be examined using multiple imputation, where missing values are replaced by a set of m plausible values using a propensity scoring sequence to generate a single estimate of the parameters of interest.⁴ Observations will first be grouped on the basis of propensity score similarity, then individuals with missing values will be randomly matched to those with observed values, and finally missing values will be randomly selected with replacement from the random sample of observed values. This sequence will be repeated sequentially starting at the 3-month follow-up observation through the 12-month follow-up observation, and the entire propensity scoring and time imputation sequence(s) will be repeated at minimum across 2-5 datasets (m) to estimate $\bar{\beta} = \frac{1}{m} \sum_{k=1}^m \hat{\beta}^{(k)}$. Sensitivity analyses will also be used to assess the robustness of primary results attributable to missing data by examining imputed and nonimputed data.

3.1.3 Dose. The treatment dose is the number of intervention components delivered to the individual student, accounting for individual students' attendance and participation. This will be tracked using the fidelity log, staff field notes, and the CAB meeting. A count, nominal, or weighted percentage will be used to represent dose pending analysis of the dose frequency distribution.

3.1.4 Baseline data analysis. Baseline data will first be analyzed to determine whether demographic and SRH variables vary relative to school (cluster). The psychometric properties of scales will be explored, and confirmatory factor analyses (CFA) for scales will be conducted. Finally, structural equation models (SEM) will

²Woertman W et al. Stepped wedge designs could reduce the required sample size in cluster randomized trials. *J Clin Epidemiol.* July 2013;66(7):752-758.

³ Kaufman C et al. Effectiveness of Circle of Life, an HIV-preventive intervention for American Indian middle school youths. *Am J Public Health.* June 2014; 104(6):e106-e112.

⁴ Fitzmaurice G, Laird N, Ware J. Generalized Linear mixed effects Models in *Applied Longitudinal Analysis*. Hoboken, NJ: John Wiley & Sons Inc.; 2004.

be developed based on the multi-level components derived from the Ecological Systems Theory model

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Nenunkumbi/Edahiyedo ("We Are Here Now"): A Multi-level, Multi-component Sexual and Reproductive Health Intervention for American Indian Youth

upon with the N/E was built. CFAs and SEMs will be conducted using Mplus software.

3.1.5 Randomization of schools. The 5 schools that AI youth from Fort Peck attend are the clusters to be randomized into the intervention, with all schools eventually being randomized to the intervention. Students and their parents/legal guardians will be recruited for baseline participation prior to randomization of the sites. Schools will be randomized to the intervention following baseline data collection using a single sequence random assignment to clusters that will determine order of intervention receipt.⁵

3.1.5 Generalized linear mixed-effects models. To test for effectiveness of the *NIE* intervention across all hypotheses under Aim 2, the generalized linear mixed-effects models (GLMM) will be used to model binary primary and secondary outcomes (condom use under H1, condom use and other sexual risks under H2) and continuous tertiary outcomes (H3) in the data. The GLMM allows for individual-level binary and continuous responses to be modeled, key covariates to be controlled for, the specification of autocorrelation within individuals, and clustering by school. The GLMM is also the most frequently employed analytic method to adjust for the longitudinal nature of SWDs,⁶ and it was chosen over the Generalized Estimating Equations (GEEs) because GEEs show inflated Type 1 error rates when the number of clusters is small, as is the case with the number of schools at Fort Peck. Hussey and Hughes proposed a mixed-effects regression approach for the SWD-CRT design,⁷ where:

$Y_{ijl} = \mu + \beta_j + \theta X_{ij} + u_i + e_{ijl}$, and where $u_i \sim N(0, \sigma_u^2)$; $e_{ijl} \sim N(0, \sigma_e^2)$, with β_j =the fixed effect of time, X_{ij} =intervention (0,1 or dose representation), θ =intervention effect, u_i =random effect for cluster, and e_{ijl} =residual for i clusters, j time periods, and l adolescents. Y_{ijl} will be modeled for SRH outcomes and interpreted in terms of a contrast of the log odds of response relative to AI youths with similar values for unobserved random effects. In order to test for changes in the tertiary outcomes, we will specify Y_{ijl} as continuous response outcomes. STATA statistical software will be used to conduct GLMMs. However, SAS will be used if more complex specification of the intraclass correlation becomes necessary.

3.1.6 7 Analysis of focus group data. Focus group data will be transcribed and coded using a partially inductive procedure. First, all transcript data will be open coded (line-by-line coding). The open codes will be pre-sorted based on whether participants are responding to acceptability or fidelity prompts. Within each implementation domain, axial codes will be developed to group the open codes, and the team will meet to discuss how axial codes saturate the pre-defined acceptability and fidelity categories. Transcripts will be coded using Atlas.ti software.

3.2 Qualitative Data Analysis. The systems level component and the FAS evaluation component of N/E will be analyzed using content analysis. Common themes will be identified from the two respective sets of data collection instruments. Coding will proceed in stages. A topical indexing scheme will be developed with input from the community advisory board members to identify the text pertaining to particular topics relevant to the systems level and FAS components of N/E. The software program, Atlas.ti will be used to construct and organize a topical indexing system of codes identifying sections of text that capture the central concepts of interests. Then, content coding will be developed by the research team with advice from the community

⁵ Esserman D, Allore HG, Trivison TG. The Method of Randomization for Cluster-Randomized Trials: Challenges of Including Patients with Multiple Chronic Conditions. *International journal of statistics in medical research*. 2016;5(1):2-7. doi:10.6000/1929-6029.2016.05.01.1.

⁶ Barker D, McElduff P, D'Este C, Campbell MJ. Stepped wedge cluster randomized trials: A review of the statistical methodology used and available. *BMC Med Res Methodol*. 2016;16:69.

⁷ Hussey M, Hughes J. Design and analysis of stepped wedge cluster randomized trials. *Contemp Clin Trials*. February 2007;28(2):182-191

advisory board to capture the content, themes, or sentiment of responses within topics. The community advisory board members will receive copies of the content coding and the content, themes, and sentiment of responses for each of the themes identified in the qualitative data collection forms. Members of the research team, including the community advisory board, will individually identify themes from all text pertaining to a specific topic are related to N/E's AIMS 2 and 3 in order to then assist the research team in developing codes to be analyzed using AtliS.ti. The codes will be reviewed and approved of by the community advisory board prior to analysis. The coding reliability for the content coding will be determined through check coding of at least 20% of the randomly chosen text within major topical categories. Once the data are coded, the themes and patterns will be summarized and interpreted. Coded text will be used to identify illustrative quotes from the qualitative data collection materials.

SECTION 4: STUDY INTERVENTION ADMINISTRATION OF DATA COLLECTION

NIE is a mixed methods study involving quantitative and qualitative methodology. There are four data collection components to *NIE*: 1) student survey (quantitative); 2) parent survey (quantitative); 3) systems level tracking (qualitative); and 4) fidelity, acceptability and sustainability evaluation (qualitative). The student survey, parent survey and systems level tracking data collection are described in section 4.1. The fidelity, acceptability and sustainability evaluation data collection is described in section 4.2.

4.1. *NIE* Intervention Components: The intervention components and corresponding modes of data collection to test efficacy of the four aspects of our intervention are shown in the table below. The left column indicates the intervention component, while the right column indicates the type of data collection and the timeline of data collection.

Intervention Component	Types of Data Collection and Timeline
Individual level: Native Stand	<ul style="list-style-type: none"> Student Surveys: baseline, 3 months, 9 months, 12 months Parent Surveys: baseline, 9 months, 12 months
Family level: Native Voices	
Community level: Cultural Mentoring	
Systems level: Enhancement of the coordination and implementation of SRH services at Fort with the Fort Peck Epi Team	<ul style="list-style-type: none"> Barriers and Facilitators Discussion Group: yearly Coordination & Implementing Monitoring Plan Tracking Log: quarterly

Subsequent to randomization of the 5 area schools to the intervention, there will be a baseline data collection from the middle of March to June 2019, followed by three waves of implementation and concurrent data collection over the next 3 years. For a visual picture of how these intervention components and methods of data collection fit into an overall Timeline, please see our Trial Timeline in the appendix.

For the student and parent/legal guardian participating in *NIE*, there are 2 forms of data collection: a student survey and a parent/legal guardian survey. Ms. FireMoon, a part-time assistant, and the N/E school outreach coordinator will oversee both surveys' administration. The student surveys and parent/legal guardian surveys will be completed using Research Electronic Data Capture or "REDCap." REDCap is a secure web application for building and managing surveys and databases.

The students and parents will take the survey on iPads that have the mobile application version of REDCap installed on the tablets. The mobile app version of REDCap collects data offline to be uploaded to an online, secure database once a secure wifi location is reached. Deidentified data will be stored virtually on the REDCap server and available for download to Genevieve Cox, Paula Firemoon, Michael Anastario, Rachel Hallum-Montes and Beth Rink. Only Paula Firemoon, the *NIE* outreach coordinator, and Genevieve Cox will have access to names linking students and parents to their records during data collection and intervention implementation. These files will be kept in a locked file cabinet by Genevieve Cox at MSU after data collection.

From Years 2-4, 456 students and one of their parents/legal guardians will participate in *NIE's* data collection. Student surveys for baseline, 3, and 9 months will be administered during regularly scheduled classes in an assigned classroom by Ms. FireMoon, the assistant, and N/E's outreach coordinator. Baseline data collection will begin in March 2019 for all schools and parents included in the intervention. Groups of 20 students at a time will be appropriately spaced in the classroom in order to ensure privacy, and survey instructions will be presented to students prior to REDCap administration. Ms. FireMoon, the assistant, and the *NIE* outreach coordinator will thoroughly review the assent form with the students, which will include a description of *NIE*, types of questions that will be asked, and potential risks and benefits of participating in *NIE*. All students will be reminded that they can withdraw at any time without consequences. Prior similar procedures have been successfully used by Dr. Rink and Ms. FireMoon for data collection in the Fort Peck schools with AI youth. For students who graduate from high school prior to the 12-month follow-up, they and their parent/legal guardian will be contacted by Ms. FireMoon to complete the 12-month follow-up (during evening hours) at the high school from which they graduated following the same procedure described above. Although data collection for the students has been designed to coincide with the school year, the same procedures will be followed if the data collection occurs when school is not in session.

Wave 1 data collection will commence in December 2019 with 1 school after students have begun receiving the Native Stand and Cultural Mentoring components of the intervention during the school year.

Wave 1 9- month follow-up will take place at the end of the school year in May/June 2020 as the intervention is completed. The Wave 1 12-month follow-up will take place at the beginning of the next school year in September 2020.

Wave 2 (2 schools) and Wave 3 (schools) will follow the same procedures and pattern of timeline of data collection. The parent survey will be administered during evening hours at the high school by Ms. FireMoon, the assistant, and N/E's outreach coordinator. All baseline parent data will be collected in Fall 2019. We will use the same REDCap administration procedures for parents/legal guardians that are described for students above. Ms. FireMoon, the assistant, and the N/E outreach coordinator will review the consent forms with the parents/legal guardians to ensure their understanding of the purpose of N/E, types of questions they will be asked, and the study's potential risks and benefits. All parents/legal guardians will be reminded that they can withdraw themselves and/or their child at any time without consequences.

Wave 1 (parents of first school) parent 9- month follow up will take place in spring of 2020. Wave 1 parent 12-month follow-up will take place in Fall 2020. Wave 2 (parents of schools 2 and 3) and Wave 3 (parents of schools 4 and 5) will follow the same procedures and pattern of timeline of data collection. Data Safety & Monitoring Plan describes participant safety and support plans

4.1.2 For the systems-level component of N/E, there are 2 forms of data collection: a barriers/facilitators discussion guide, and a coordination and implementation monitoring plan tracking log.

These 2 forms of data collection span the 8 service domains relative to improving SRH services for adolescents as outlined by the CDC. The barriers/facilitators discussion guide will be administered in a group discussion format to the Epi Team at baseline and at 12 months during a standing monthly meeting held at the Fort Peck Tribal Headquarters to assess the factors that impede or strengthen the provision of SRH services for AI youth at Fort Peck. The Epi Team's discussion of the barriers/facilitators will be recorded and transcribed. Based on findings from the barriers/facilitators guide, a coordination and implementation monitoring plan will be developed in the form of a tracking log, in order to monitor improved coordination and provision of SRH services. The coordination and implementation monitoring plan tracking log will be completed as part of the baseline data collection and tracked quarterly during a regular monthly meeting of the Epi Team. Dr. Rink and Ms. FireMoon will be the primary research staff-with assistance from two of N/E's consultants, Ms. Adriann Ricker and Dr. Rachel Hallum-Montes-to collaborate with the Epi Team in completing the barriers/facilitators discussion guide, developing the implementation monitoring plan, and tracking the plan's progress toward increasing access to SRH services for AI youth. No identifying data or participants will be collected.

4.1.3 Incentives: Incentives for the students and parents/legal guardians are based on discussions with N/E's Community Advisory Board and members of the FPCC research team, as well as Dr. Rink's prior experience with research studies involving Indigenous communities. Students will receive \$10 at the baseline, 3-month, and 9-month data collections and \$20 at the 12-month data collection. Parents/legal guardians will receive \$10 at the baseline and 9-month data collections and at each of the 4 sessions of Native Voices, plus \$20 at the 12-month data collection. Similar incentives for students and parents have been previously successful. Epi Team members will not receive incentives for participation in N/E, as it is part of their tribal employment responsibilities.

4.2 Fidelity, Acceptability and Sustainability Data Collection. Fidelity recommendations from the National Institutes of Health Behavior Change Consortium will be implemented across the 5 areas of study design, component leader training, delivery of treatment, receipt of treatment, and enactment of treatment skills. The Fidelity, Acceptability, and Sustainability (FAS) of the N/E intervention will be emphasized with a variety of internal processes and data collection methods. The left column describes the FAS component, while the right column describes the corresponding type of data collection and timeline of data collection.

Fidelity, Acceptability, and Sustainability Component	Types of Data Collection and Timeline
Community Advisory Board (CAB) meetings	<ul style="list-style-type: none"> • CAB FAS Meeting Form: quarterly • CAB meeting notes: quarterly
Team-wide meetings	<ul style="list-style-type: none"> • Team-wide meetings FAS Form: bi-monthly
Consistency of staff training	<ul style="list-style-type: none"> • Staff training evaluation log: yearly
FAS of coordination/implementation enhancement of Epi Team	<ul style="list-style-type: none"> • Fidelity Reach Log/Staff Field notes: monthly
Intervention implementation of Native Stand, Native Voice, and Cultural Mentoring	<ul style="list-style-type: none"> • Fidelity Reach Log/Staff Field notes: each day of intervention
Community level FAS	<ul style="list-style-type: none"> • 8 Focus Groups (2 youth, 2 parent, 2 regarding Cultural mentoring, 2 professionals): yearly beginning in Year 3 (Total of 24 Focus Groups)

4.2.1 FAS Data Collection: In consultation with Dr. Hallum-Montes, Dr. Rink, Dr. Cox, and Ms. Firemoon developed four forms to collect FAS data during the implementation of the intervention.

Forms:

1.) The "Community Advisory Board Meeting Form" will be collected once per quarter after each meeting of the CAB. It will document the barriers and facilitators to intervention implementation discussed at CAB meetings, any social, environmental, political, or bureaucratic contextual factors such as the death of an elder or Tribal Council election year, that may have inhibited or facilitated intervention implementation, and any suggestions to mitigate these barriers the CAB discusses. CAB meeting notes will also be taken during each meeting.

2.) The "Whole Team Meeting Form" will document bi-monthly meetings that include Paula Firemoon, Beth Rink, Adriann Ricker, Ramey Growing Thunder, the N/E outreach coordinator, the Cultural Mentor outreach coordinator, and Genevieve Cox. This form will include any barriers and facilitators to intervention implementation discussed, contextual factors (social, environmental, political, or bureaucratic) discussed, suggestions, and who will be responsible for implementing these suggestions.

3.) The "Staff Training Evaluation Log" will be collected yearly and documents who has been trained, what procedures were followed during training, problems encountered during trainings, and any feedback from the trainings.

4.) The "Fidelity Reach Log and Field Notes" form includes documenting the delivery of the intervention and any field observations study staff note. It will document the date of the intervention, the length of time the intervention was delivered, specific modules delivered, and any barriers and facilitators to the delivery of the intervention.

The outreach coordinator will also document any environmental, social, political, or bureaucratic barriers or facilitators and suggested solutions to the intervention delivery. With the exception of names of staff trained, no identifying data will be collected. These files will be kept in a locked file cabinet by Genevieve Cox at MSU after data collection.

In addition to the 4 FAS forms, we will implement 8 focus groups at 12 months from inception of the intervention for each year of the 3 years of planned intervention implementation (a total of 24 focus groups). The focus groups will include 6 to 8 individuals per group. The 8 focus groups will consist of 2 focus groups with youth, 2 focus groups with parents, 2 focus groups with the cultural mentors, and 2 focus groups with professionals from schools, agencies, and health care organizations that are involved in N/E. The focus groups will be recorded and transcribed. Written consent will be obtained from the adults participating in the fidelity and acceptability focus groups. Written consent and assent will be obtained from the parents/legal guardians and their child, respectively, in order for the child to participate in the focus groups. Focus group participants will receive a \$20 incentive. No identifying data will be collected.

SECTION 5: SELECTION AND ENROLLMENT OF PARTICIPANTS

4.1 Inclusion Criteria. To be eligible for inclusion in *NIE*, students must be: 1) 15 to 18 years old; 2) a registered member of a federally recognized tribe or an associate tribal member; and 3) a resident of Fort Peck with a parent/legal guardian. For inclusion in the systems-level component of *NIE*, only those staff members who sit on the Epi Team as representatives of their respective agencies are eligible. Written informed consent will be obtained from the head of each agency represented on the Epi Team and the staff member participating in the Epi Team.

4.2 Exclusion Criteria. Exclusion criteria are minimal due to the CAB's value of inclusion in *NIE*. Exclusion criteria include: 1) not meeting the aforementioned inclusion criteria; and 2) having a medically identified physical or cognitive impairment that would impede their understanding of and participation in the educational content and activities of *Native Stand*, *Native Voices*, and the cultural mentoring program.

4.3 Study Enrollment Procedures. Students and their parent/legal guardian will be recruited from each of the study's 5 schools. Based on discussions with school personnel and our previously successful recruitment strategies, recruitment will occur via flyers posted in the schools, letters to the parents, parent-teacher meetings, and word of mouth. Additionally, a parent/legal guardian session that provides an overview of *NIE*, the content and format of the intervention components, and risks and benefits of participation will be held at each of the study's 5 schools. Students and their parents/legal guardians, and students from each cluster, will be recruited for participation at baseline. Students and their parents/legal guardians will be recruited for baseline participation **prior to randomization of the sites**. Students and parents/legal guardians will be assigned unique study identification numbers. No persons who refuse to participate in the study, in whole or in part, will be coerced to engage in any study activity. After written consent and assent is obtained from the parent/legal guardian and child, respectively, they will be enrolled in the study.

SECTION 6: HUMAN SUBJECTS

6.1 Institutional Review Board Approvals. The study has approval from the Fort Peck Institutional Review Board and the Montana State University Institutional Review Board. In addition, the study has been registered with ClinicalTrials.gov. These aforementioned approvals are in agreement with the conditions for approval to conduct human subjects research as outlined in our Notice of Grant Award from the National Institute of Minority Health & Health Disparities. See Appendices for research approvals.

5.2. Human Subjects' Characteristics. There three groups participating in the study in which data will be collected include: 1) 15 to 18-year-old youth; 2) a parent/legal guardian; and 3) members of the Fort Peck Epi Team.

6.3. Data Sources for Human Subjects Based on Intervention Levels. Our study includes four levels of intervention:

1) Individual Level. Native Stand is a school-based, 27-module STI-, HIV-, and teen pregnancy-prevention curriculum, originally developed for rural white youth and adapted for Native youth in 2008. For our study, an adaptation of Native Stand will be implemented over 9 months in the 5 tribal high schools to educate Fort Peck tribal youth on sexual risk behavior prevention strategies by tailoring and reducing the 27 modules into 18 modules, as well as including specific community-relevant traditional and contemporary cultural lesson plans. Trained project staff will deliver Native Stand in school classroom settings during the school year as part of each school's curriculum. American Indian students only will be recruited for Levels 2 and 3 and for data collection.

2) Family Level. Native Voices is a video-based HIV/STI prevention intervention designed for AI adolescents, which includes condom use, negotiation skills, group discussion, and role playing. Native Voices will be adapted from 1 module into 4 modules, as recommended by the creators of Native Voices for curriculum adaptations involving family members, and will involve students and one of their parents/legal guardians. Our adaptation of Native Voices promotes discussions between the students and their parent/legal guardian regarding STI, HIV, HCV, and pregnancy prevention relevant to the Fort Peck tribal community. Ms. FireMoon will implement Native Voices to groups of 10 students and their parents/legal guardians at one time at the local high school for 2 hours in the evening. Native Voices' 4 modules will be implemented over 9 months.

3) Community Level. The third level of our study is a cultural mentoring component that pairs AI youth with older adults and elders to discuss traditional American Indian beliefs and practices about reproductive health. To our knowledge, no mentoring programs have been designed for AI youth that specifically address sexual and reproductive health issues. The mentoring program is based on Assiniboine and Sioux traditional knowledge and the National Mentoring Partnership standards for mentoring. The mentoring program was designed specifically for Fort Peck youth by the Fort Peck Tribes' Language and Cultural Department and has been in existence for 5 years. Our study integrates this cultural mentoring program into our study's overall framework. Our cultural mentoring program will include older male and female tribal members from the Assiniboine and Sioux tribes. The older adults will be paired with the youth participating in the intervention by gender and tribal affiliation. Students participating in Native Stand and Native Voices with their parent/legal guardian will meet monthly over the course of 9 months one-on-one with their mentor and monthly in mentor mentee small groups. Topics addressed in the cultural mentoring program include overall information on Assiniboine and Sioux cultural beliefs, values, and ceremonies, as well as more specific information on Assiniboine and Sioux cultural beliefs and values regarding sex, having children, parenting, and relationships.

4) Systems Level. The fourth level of our study is a community-level strategy that involves mobilizing a network of education, health care, and social service agencies at Fort Peck to coordinate reproductive health services for 15- to 18-year-old AI youth over a 12-month period. The systems-level approach will utilize existing tribal infrastructure by enhancing the work of the established Fort Peck Tribal Epidemiology Team (Epi Team). The Epi Team is a local committee made up of the Fort Peck Tribal Health Department; Indian Health Service (Poplar Service Unit and Wolf Point Service Unit); the Roosevelt County Health Department; and school nurses from the Fort Peck Health Promotion and Disease Prevention Program. The Epi Team meets monthly and has been in existence for 15 years with the purpose of monitoring diseases on the reservation and the health status of the Assiniboiné and Sioux tribes. As part of N/E, the Epi Team is tasked with improving the coordination and implementation of STI, HIV, and HCV screening, condom distribution, contraceptive services, and pregnancy testing on the Fort Peck Reservation.

5.3.1. Data Collection Materials for Human Subjects. For the individual-, family-, and community-level components of N/E, there are two forms of data collection: a student survey administered at baseline and at 3, 9, and 12 months after intervention inception, and a parent/legal guardian survey administered at baseline and at 9 and 12 months after intervention inception. The student survey will assess participation in Native Stand, Native Voices, and the cultural mentoring program. The parent survey will assess participation in Native Voices. Ms. FireMoon and the study's outreach coordinator will oversee the administration of the student surveys and the parent/legal guardian surveys. The student surveys and parent/legal guardian surveys will be completed utilizing REDCap. Between Years 2-4, 456 students and one of their parents or legal guardians will participate in N/E's data collection. Student surveys for baseline, 3 months, and 9 months will be administered to groups of 20 students at a time during regularly scheduled classes in an assigned classroom by Ms. FireMoon and the study's outreach coordinator. During data collection, groups of 20 students will be appropriately spaced in the classroom in order to ensure privacy, and survey instructions will be presented to students prior to REDCap administration. Ms. FireMoon and the study's outreach coordinator will thoroughly review the assent form with the students at the baseline data collection, which will include a description of N/E, types of questions that will be asked, and potential risks and benefits of participating in N/E. All students will be reminded that they can withdraw at any time without consequences. For students that graduate from high school prior to the 12 months data collection, they will be contacted by Ms. FireMoon directly to complete the 12 months data collection (during evening hours) at the high school they graduated from following the same procedure described above. This same procedure will be followed if the data collection time point occurs for some reason when school is not in session. The parent survey will be administered during evening hours at the high school in an assigned classroom by Ms. FireMoon and the study's outreach coordinator. We will use the same REDCap procedures for parents/legal guardians that are described for youth above. In addition, written consent will be obtained from the parents/legal guardians prior to their participation in the study. Ms. Firemoon and the study's outreach coordinator will review the informed consent with the parents/legal guardians at the time of data collection.

For the systems-level component of N/E, there are two forms of data collection: a barriers/facilitators discussion guide and a coordination and implementation monitoring plan tracking log. These two forms of data collection span the 8 service domains relative to improving SRH services for adolescents as outlined by the Centers for Disease Control and Prevention (CDC). The barriers/facilitators discussion guide will be administered in a group discussion format to the Epi Team at baseline and at 12 months during a standing monthly meeting held at the Fort Peck Tribal Headquarters to assess the factors that impede or strengthen the provision of SRH services for AI youth on the Fort Peck Reservation. The Epi Team's discussion of the barriers/facilitators will be recorded and transcribed. Based on findings from the barriers/facilitators guide, a coordination and implementation monitoring plan will be developed in the form of a tracking log in order to

monitor improved coordination and provision of SRH services. The coordination and implementation monitoring plan tracking log will be completed as part of the baseline data collection and tracked at 3, 6, 9, and 12 months during a regular monthly meeting of the Epi Team. In collaboration with the Epi Team, Ms. FireMoon, Ms. Adriann Ricker, and Dr. Rink will complete the barriers/facilitators discussion guide, develop the implementation monitoring plan, and track the plan's progress toward increasing access to sexual and reproductive health services for American Indian youth on the Fort Peck Reservation.

All students attending each school will be eligible to participate in the individual-level Native Stand curriculum, as it will be incorporated into that school's regular curriculum. In order to be eligible for inclusion in the family and community-level components of N/E and the data collections, students must be: 1) 15 to 18 years old; 2) a registered member of a federally recognized tribe or an associate member; 3) a resident of the Fort Peck Reservation with a parent/legal guardian; and 4) enrolled at one of the five schools participating in N/E.

Exclusion criteria are minimal due to the value the CAB places on inclusion in N/E's program implementation. Exclusion criteria include 1) not meeting the aforementioned inclusion criteria, and 2) having a physical or cognitive impairment that would impede the student's understanding of and participation in the content of Native Stand, Native Voices, and the cultural mentoring program. Study-enrolled students must agree at the outset to participate in Native Stand, Native Voices, and the cultural mentoring program, and agree to complete the survey at baseline and at 3, 9, and 12 months during and shortly after their cluster's program. Parents/legal guardians must also agree to participate in Native Voices and complete the parent/legal guardian survey at baseline and at 9 and 12 months. No persons will be coerced to engage in any study activity, and anyone may refuse to participate at any time. After written consent and assent are obtained from the parents/legal guardians and their children, respectively, they will be enrolled in the study. For inclusion in the systems-level component of the study, only those staff members who sit on the Epi Team as representatives of their respective agencies are eligible. Written informed consent will be obtained from the head of each agency represented on the Epi Team and the staff member participating in the Epi Team.

If at any point in the study a student discloses abuse, they will be referred to the appropriate person or organization. For example, a research participant who is under the age of 18 and in school who discloses that he or she is being abused at home will be referred to the counselors in the school for assistance, with the possibility of joint reporting to Child Protective Services. Students will be informed during the informed consent process that any abuse they may disclose will be reported, since the members of the research team and the interviewers are mandated reporters.

Another form of data collection that involves human subjects is related to Aim 3 of our study, which is to evaluate the fidelity and acceptability of N/E. As part of Aim 3 we will conduct focus groups. We will implement 8 focus groups at 12 months from inception of the intervention's curricular components for each year of the 3 years of planned intervention implementation (a total of 24 focus groups). The focus groups will include 6 to 8 individuals per group. The 8 focus groups will consist of 2 focus groups with youth, 2 focus groups with parents, 2 focus groups with the cultural mentors, and 2 focus groups with professionals from schools, agencies, and health care organizations that are involved in N/E. Written consent and assent will be obtained from adults, parents/legal guardians, and youth, respectively. Focus groups will be recorded and transcribed. No names or other identifying information, such as an address, will be included on the transcripts. However, age and gender will be recorded. After each focus group, the focus group facilitator will check the audiotapes for clarity. Clear audiotapes will be transcribed. Audiotapes that are not sufficiently clear, or do not have adequate volume to transcribe, will not be transcribed. Instead, responses typed or directly written down by the focus group guide during the interview will be used as the transcript for content analysis. Names of students or others identified in the transcripts will be blacked out in order to ensure confidentiality.

6.3.2. List of Data Source Materials and Measures (Table 2 below).

Student Survey: To assess students' participation in N/E, we draw from several existing measurements that have been implemented and validated in research studies with AI youth. Primary outcome measure: Condom use will measure frequency of condom use relative to frequency of sex during sexual intercourse using questions derived from the Risk Behavior Assessment. Secondary outcome measures: These will include the number of sex partners; age of onset of sexual intercourse; frequency of sexual intercourse; pregnancy history; frequency and type of birth control used during sexual intercourse relative to the frequency of sexual intercourse; and frequency and types of substance use (cigarettes, marijuana, alcohol, and methamphetamine). Tertiary outcome measures: Parent/legal guardian communication is measured by the frequency and types of SRH topics that parent/legal guardian and child discussed. Cultural identity is measured using two established measurements: One measure assesses the extent to which a student identifies with his or her American Indian culture and feels cultural pride, and the other measure assesses frequency and type of participation in cultural activities. Access to SRH services is measured by frequency and type of SRH service used (ever been tested for STIs and follow-up, ever been tested for HIV and follow-up, ever been tested for HCV and follow-up, ever been pregnant/gotten someone pregnant and follow-up). Other variables to be measured in N/E that assess attitudes, intentions, skills, and mental health are: Motivation to avoid STIs, HIV, HCV, and pregnancy, as measured by asking students how important it is to them to keep themselves (or someone else) from getting an STI, HIV, and HCV, and how important it is to them to keep from getting pregnant or getting someone pregnant. Intention to use condoms and/or birth control is measured by asking students how likely it is they will use condoms and/or birth control the next time they have sexual intercourse. Intention to abstain from sex is measured by asking students how likely it is that they will not participate in sexual intercourse. Condom and birth control use self-efficacy is measured by assessing confidence in one's ability to use condoms and birth control. Refusal skills regarding sex are assessed by how strongly students believe they can say no to sex. Knowledge about STIs, HIV, HCV, pregnancy, and healthy relationship characteristics are measured using true/false/don't know questions. Mental health is assessed using two established measures: One measure assesses depression using the C-ESD, and the other measurement assesses exposures to stressful life events by assessing lifetime occurrences of a series of negative events. Standard demographic measures in the student survey are age, gender, sexual orientation, school, and highest grade completed.

Parent/Legal Guardian Survey. The parent/legal guardian survey is based on parents'/legal guardians' participation in Native Voices. It includes a list of SRH topics about which the parent/legal guardian has spoken to the child and the frequency of times discussed. The parent/legal guardian measures have been validated in previous studies evaluating parent/child SRH communication and have been used by Dr. Rink in her Greenland studies. The SRH topic list and frequency is the same as in the student survey, only adapted for parents/legal guardians. Standard demographic measures included in the parent/legal guardian survey are age, gender, marital status, highest grade completed, and occupation.

Barriers/Facilitators Discussion Guide. The barriers/facilitators discussion guide is a qualitative assessment using open-ended questions that address the factors impeding and facilitating SRH services for AI youth on the Fort Peck Reservation. The guide is based on the 8 service domains for evidence-based clinical practices outlined in the CDC's Contraceptive and Reproductive Health Services for Teens: Evidence-based Clinical Best Practices Guide(80-82)-namely, contraceptive access; provision of hormonal contraception/IUD; emergency contraception; cervical cancer screening; STI/HIV/HCV testing and treatment; cost, confidentiality, consent; health center infrastructure; and health center environment.

Coordination and Implementation Monitoring Plan Tracking Log. The tracking log will monitor the progress toward completion of the 8 SRH service domains identified from the barriers/facilitators discussion

guide and corresponding evidence-based clinical practice elements.

Focus Groups. Data collection related to Aim 3 of our study, which is to evaluate the fidelity and acceptability of N/E, includes a focus group guide, as described above. The Aim 3 focus groups will include questions such as what experiences/activities they liked and/or did not like about the intervention, what educational information they did and/or did not like about the intervention, and what recommendations they have for improving the intervention.

Table 2. NIE Measures.

Table 2. N/E Measures.

Data Collection Instruments and Measures	Data Collection: Baseline & Months				Description of Measures
Student Survey	Base	3	9	12	Number of Items; Scale Anchors; Benchmark Values
Primary Outcome Variable					
Proportion of condom use during sexual intercourse (SI)	X	X	X	X	2 items; number of times condom used relative to number of times had SI
Secondary Outcome Variables					
Age of onset of sexual intercourse	X	X	X	X	2 items; ever had SI & age at first SI
Number of sex partners	X	X	X	X	2 items; lifetime & past-month sex partners
Frequency of sexual intercourse	X	X	X	X	1 item; frequency of SI in past month
Pregnancy history	X	X	X	X	1 item; number of pregnancies
Type & frequency of birth control (BC) during sexual intercourse	X	X	X	X	3 items; type of BC use and number of times BC used during SI
Type & frequency of substance use (SU) during sexual intercourse	X	X	X	X	1 item measures SU with SI; 5 items measure lifetime and past month SU
Tertiary Outcome Variables					
Type & frequency of parent/legal guardian-child SRH communication	X	X	X	X	24 items Likert scale; higher score = higher communication
Cultural identity & participation in cultural activities	X	X	X	X	3 items cultural identity ($\alpha = .75$); 2 items cultural activities engagement ($\alpha = .46$)
Type & frequency of SRH services	X	X	X	X	9 items; frequency, type, and follow-up of SRH services used
Other Variables					
Motivation to avoid STIs, HIV, HCV, & pregnancy	X	X	X	X	Up to 9 items; 1 (very true) to 5 (very untrue); 1 = more positive attitude/motivation
Condom & birth control use intention & self-efficacy	X	X	X	X	4 items per intention; 1 (very true) to 5 (very untrue); 1 = higher intention; 6 self-efficacy items; 1 (very easy) to 4 (very hard); 1 = high self-efficacy
Abstinence	X	X	X	X	3 items; 1 (strongly disagree) to 4 (strongly agree); 4 = more supportive of teen abstinence
Refusal skills regarding sex	X	X	X	X	7 items; 1 (I definitely can say no) to 5 (I definitely can't); 1 = stronger refusal skills
Knowledge of STIs, HIV, HCV, pregnancy, & health relationships	X	X	X	X	Range of 4 to 10 items per topic; True/False/DK; Average proportion of questions correct
Depression (CES-D) & exposure to stressful life events	X	X	X	X	CES-D — 7 items ($\alpha = .80$); Life Events — 24 items; Yes/No; number of events observed
Student Demographics					
Age, gender, sexual orientation, school, highest grade completed	X	X	X	X	4 items
Parent/Legal Guardian Survey					
Type & frequency of parent/legal guardian-child SRH communication	X		X	X	24 items Likert scale; higher score = higher communication
Parent/Legal Guardian Demographics					
Age, gender, marital status, highest grade completed, occupation	X		X	X	5 items
Barriers/Facilitators Discussion Guide					
8 Service Domains for Evidence-Based Clinical Best Practices	X			X	Open-ended questions about barriers/facilitators for: contraceptive access, provision of hormonal contraception/IUD, emergency contraception, cervical cancer screening, STI/HIV/HCV testing and treatment, cost confidentiality, consent, health center infrastructure, & health center environment.
Coordination & Implementation Monitoring Plan Tracking Log					
8 Service Domain Elements	X	X	X	X	Tracks action steps, timeline, and responsible party

6.4 Potential Risks

There may be minor risks to agreeing to participate in N/E. Student and parent/legal guardian participants may be asked some questions that make them feel uncomfortable, sad, or confused (e.g., questions about sexual risk behaviors). For participants in the systems-level component of the study that evaluates the enhancement of the coordination of SRH services, we anticipate low to no risks, since none of the data being collected will be of a personal nature. For Aim 3, which uses focus groups as one method of data collection to evaluate the fidelity and acceptability of N/E, we also anticipate low to no risk, since none of the data being collected will be of a personal nature. All study participants will be informed that they may choose to stop their participation in N/E at any time or decline to answer a particular question asked of them on a data collection instrument or during a data collection process. We will inform study participants that the study is voluntary and that they can withdraw from the study, by stating that they want to do so, at any time over the course of the study.

6.4.1. Adequacy of Protection Against Risks

Nenunkumbi/Edahiyedo ("We Are Here Now?": A Multi-level, Multi-component Sexual and Reproductive Health Intervention for American Indian Youth

A. Recruitment and Informed Consent

The high schools in Frazer, Wolf Point, Poplar, Brockton, and Culbertson will serve as the primary recruitment sites for our study. Based on discussions with school personnel and our previously successful recruitment strategies, recruitment will occur via flyers posted in the schools, letters to the parents, parent-teacher meetings, and word of mouth. Additionally, a parent/legal guardian session that provides an overview of N/E, the content and format of the intervention components, and risk and benefits of participation will be held at each of the study's 5 schools. Students and their parents/legal guardians from each cluster will be recruited for participation at baseline (Q2 of Year 2). At the time of the student data collection at baseline, Paula FireMoon and the study's outreach coordinator will thoroughly review the assent form with the students, which will include a description of the N/E curricular components, types of questions that will be asked in the data collection, and potential risks and benefits of participating in N/E. All attempts will be made to help the students understand the nature of the study. Paula FireMoon and the study's outreach coordinator will thoroughly review the consent forms with the parents, which will include a description of N/E, types of questions that will be asked, and potential risks and benefits of participating in N/E. Parents will provide informed consent for their child as well as for themselves prior to their participation in the Native Voices curriculum. For the systems-level component, Epi Team members will complete an informed consent at the time of the first barriers and facilitators discussions in Year 2. If members change from one such discussion to the next, new informed consents will be collected as needed. For the Aim 3 focus groups, informed consent will be obtained from the mentors or the professionals representing agencies prior to their participation in the focus groups as key stakeholders. Consent and assent will be obtained from parents/legal guardians for their participation in a parent group, and from parents/legal guardians and their children, respectively, for the children's participation in a children's focus group. All study participants, both adults and children, will be reminded that they can withdraw at any time without consequences. No study participant will be coerced to participate in the study, in whole or in part. Human subjects approval has been received from the Fort Peck IRB for the Year/Aim 1 refining, tailoring, and finalizing the intervention design. At that point, new applications to the Fort Peck IRB and the MSU IRB will receive approvals prior to study start.

B. Protection Against Risk

Because N/E involves children ages 15 to 18 years old, we will ensure that parents/legal guardians understand the research protocol and are able to provide informed consent for themselves and their participating children in this minimal-risk intervention study. To preserve confidentiality, all data collection forms will be coded with a unique identifier. All of the project data, including the audiotapes and transcripts, will be labeled with study identification numbers and stored separately from the informed consent forms. Consent forms will be kept in a locked file cabinet in Paula FireMoon's office at Fort Peck Community College, which has a combination lock on the door that only Paula FireMoon knows. All survey data will be stored in a password-protected file on a password-protected computer at Fort Peck Community College in Paula FireMoon's office. Focus group documents will be uploaded onto MSU's Box server, a password-protected cloud data storage system. All of the project data-including the audiotapes, transcripts, and interview summaries with study identification numbers-will be stored separately from the informed consent forms in a locked file cabinet in Dr. Rink's locked office at Montana State University, to which only Dr. Rink and the MSU-based research program manager, Genevieve Cox, will have access. Once the focus groups have been transcribed and checked for validation against the audiotapes, the audiotapes will be destroyed in order to ensure no voice recognition. At the end of the project, all of the deidentified data files (though not individual surveys) will be returned to Fort Peck Community College and stored in the Fort Peck research archives in Poplar, Montana, as is required by the Fort Peck IRB. Please note that none of the data returned to Fort Peck Community College will contain a study participant's name or contact information to ensure that personal information collected during the study is not associated with a study participant's name. Data files at Fort Peck Community College will be kept in

accordance with federal law regarding research material. Also, the study participants (completing surveys or participating in focus groups) will be informed of where the data will be stored during the informed consent process. All data will be kept in accordance with federal law requirements regarding research material.

SECTION 7: DATA SAFETY MONITORING PLAN

This plan describes the general data and safety monitoring procedures for the proposed research activities, including the responsibilities of the PI, Co-Investigators, and the Community Advisory Board, as well as the reporting of adverse events. This data safety monitoring plan was submitted with our R01 proposal and approved by the review panel, project officer and grants management officer at NIH. Protocols for data safety have also been reviewed and approved by the Fort Peck and Montana State University Institutional Review Boards.

The principal investigator, Elizabeth Rink, Ph.D., the Fort Peck-based project director Paula FireMoon, M.Ed. (co-investigator), and the Fort Peck Tribes' Language and Culture Department director Ramey Growing Thunder, MA (co-investigator), will be responsible for knowing and adhering to the cultural protocols and official policies of the Fort Peck Tribes and the five participating high schools; the Fort Peck IRB policies and procedures; and the MSU IRB policies and procedures. Dr. Rink will be the lead on the Fort Peck and MSU IRB correspondences and reports. She will maintain accurate documentation of the Fort Peck and MSU IRB correspondences and reports on her password-protected desktop computer in her locked office at MSU. The PI and the local Fort Peck co-investigators (FireMoon and Growing Thunder), who together will oversee the intervention at Fort Peck, are responsible for documentation and handling of all possible study-related adverse events. They all are experienced in conducting research and implementing and evaluating community based programs with American Indian youth. Rink and FireMoon have experience conducting such research related to sexual and reproductive health. All will assure that data collection and safety monitoring systems are in place and implemented-Mrs. Growing Thunder for the mentoring program and Ms. FireMoon for the other intervention components.

The Data and Safety Monitoring Plan includes the following descriptions:

1. Potential adverse events resulting from participation;
2. Procedures to safeguard against those events;
3. Response procedures for adverse events;
4. Reporting procedures for adverse events;
5. Oversight.

1. Potential Adverse Events Resulting from Participation

- A. Possible violation of confidentiality;
- B. Possible violation of cultural protocols or official policies;
- C. Possible discomfort due to completing data collection tools;
- D. Possible embarrassment in disclosing personal sensitive information;
- E. Possible disclosure of information about intended physical harm to victims, or abuse of children, that would need to be reported to the child welfare agency, and an investigation of the allegations(s) and further action, as indicated, that could ensue;
- F. Possible dissatisfaction with completing the data collection tools;
- G. Possible dissatisfaction with the intervention activities.

2. Procedures to Safeguard Against Adverse Events

All data collection protocols include a form on which the research team will record any problems with the data collection, concerns about the adolescents, or unusual occurrences during the conduct of the intervention or the collection of data. These forms allow the team to quickly review and respond to any possible concerns or adverse effects. The form includes contact information for Rink, FireMoon, and Growing Thunder. One or more of them will always be available during data collection. During phone conferences and meetings (weekly during the intervention periods and monthly otherwise), all problems and concerns will be discussed and processed among themselves, and with other project personnel as needed.

A. Informed Consent: Ms. FireMoon and the N/E outreach coordinator will review the consent forms with the parents/legal guardians at baseline to ensure their understanding of the purpose of N/E, types of questions they will be asked, and the study's potential risks and benefits. They will be reminded that they can withdraw themselves or their child at any time without consequences. Likewise, Ms. FireMoon and the study's outreach coordinator will thoroughly review the assent form with the 456 students to be enrolled, which will include a description of N/E, types of questions that will be asked, and potential risks and benefits of participating in N/E. All students will be reminded that they can withdraw at any time without consequences. After written consent and assent are obtained from the parents/legal guardians and their child, respectively, they will be enrolled in the study. For inclusion in the systems level component of the study, only those staff members who sit on the Epi Team as representatives of their respective agencies are eligible. Written informed consent will be obtained from the head of each agency represented on the Epi Team and the staff member participating in the Epi Team. Written consent and assent will be obtained from the maximum of 192 adult professionals, parents/legal guardians, and youth, respectively, for participation in the 24 planned focus groups. All study participants will be informed of where and how the data will be stored during the informed consent process.

B. Confidentiality and Data Safeguards: To ensure confidentiality, all information will be coded using a unique identification number so that it cannot be associated with any individual. All of the survey data will be labeled with study identification numbers and stored separately from the informed consent forms in a locked file cabinet in Paula FireMoon's locked office at Fort Peck Community College. A master sheet, with individual names and their respective unique study identification numbers, will be kept in a separate locked file that can be accessed only under supervision of the PI or Project Director. The data collection from the student surveys and parent/legal guardian surveys will be downloaded using the RedCap software into the MSU Box server, a file-sharing cloud server, for storage. This is a password protected virtual storage system for de-identified research materials that only specified invited individuals (members of the research team) may view. The audiotapes of the focus groups will be stored separately from the informed consent forms in a locked file cabinet in Dr. Rink's locked office at Montana State University. All other focus group data including the de-identified transcripts, interview summaries, and the results of the content analysis will be stored on the MSU Box server. All data entered into Box as part of the project's computerized database will be identified by unique identification number only. The entire research team and all other project personnel who come in contact with data or with the human subjects of the intervention will sign a formal oath of confidentiality. The information gathered will be used only for scientific, program evaluation, or instructional purposes. No information about the identities of study participants will be published or presented at conferences.

C. Cultural Protocols and Tribal/School/ Policy Safeguards: Dr. Rink and Ms. FireMoon will be responsible for working with the study's CAB, other investigators, and consultants to ensure that the intervention adheres to the cultural protocols and official policies of the Fort Peck Tribes; the Fort Peck IRB policies and procedures; and the MSU IRB policies and procedures. Tribal elders will be consulted on traditional topics and protocols that cannot otherwise be addressed by Ms. FireMoon, the study's CAB members, and Mrs. Growing Thunder. Dr. Rink and Ms. FireMoon will hold quarterly meetings with the study's CAB. All documents related to N/E will be developed, reviewed, and vetted by the study's CAB members as necessary during the quarterly CAB

meetings. Similarly, all data resulting from N/E will be reviewed, interpreted, and approved by the CAB. If necessary, Dr. Rink and Ms. FireMoon will also meet individually with CAB members to discuss the study's research protocols, data collection instruments, and findings. In addition to the CAB-related meetings, Dr. Rink, Ms. FireMoon, and Mrs. Growing Thunder will hold monthly team meetings to discuss the study's research protocols, implementation strategies and progress, research-related documents, data collection procedures, and analysis. Any concerns brought up by the CAB or other members of the research team will be discussed until a resolution is reached.

As part of N/E we will use fidelity and acceptability recommendations from the National Institutes of Health Behavior Change Consortium. These recommendations address study design, component leader training, delivery of treatment, receipt of treatment, and enactment of treatment skills. In order to assess the fidelity and acceptability of N/E, data sources will include: staff training logs, fidelity reach logs, staff field notes, notes from discussions at monthly team meetings, and notes from discussions with CAB members and at CAB meetings. Focus groups are an additional qualitative measure to assess fidelity and acceptability. These fidelity and acceptability data sources will assist the MSU based and FPCC-based research teams and the CAB to monitor the enrollment of students and parents/legal guardians into the study, monitor the data submission, quality-check the data being reported, avoid potential study related bias or inconsistencies, and prepare interim reports when necessary.

D. Mandatory Reporting Safeguards: Procedures to prevent the violation of confidentiality will be limited by mandatory reporting requirements. Subjects will be informed in the consent document that the research team must report to authorities: (1) physical injury to any child caused by other than accidental means; and (2) information from a study participant that leads the research team to believe a person is in imminent danger of physical harm. The project personnel will inform parents or guardians if, in the judgment of the research team/project personnel, their child (under 18) is in imminent danger of trying to harm him/herself.

E. Research Team Safeguards: All research team/project personnel who interface in any way with intervention protocols, data collection, or data analysis are required to complete and be up-to-date with the extensive Collaborative Institutional Training Initiative (CITI) training and testing program and the NIH Good Clinical Practice Training. Weekly or monthly meetings or phone conferences will occur among the key personnel for ongoing training, monitoring of protocols, and problem solving. Questions concerning data collection will be processed during this time. The Project Director (Ms. FireMoon) will coordinate and oversee all activities at the data collection sites and will report all activities, concerns, and questions to the PI on an ongoing basis. Prior to the start of the intervention cycle, the entire team on the ground in the Fort Peck communities, including personnel to be hired, will be trained to identify events that would fall under mandatory reporting guidelines. These include physical injury to any child caused by other than accidental means, or information from a student participant that leads staff to believe a person is in imminent danger of physical harm.

F. Discomfort with Completing Intervention Data Collection Instruments or Disclosure Safeguards: During the course of participation in the research, a participant may have questions concerning the data collection tools. Either the Project Director (Ms. FireMoon) or the Outreach Coordinator (to-be-hired) will be available at each school data collection event to answer questions. Likewise, the mentoring program Director (Mrs. Growing Thunder) and her Community Mentorship Coordinator (to-be-hiredDo you want to add name?) will be available at each group mentoring meeting to answer questions. To prevent discomfort or embarrassment, the Project Director (Ms. FireMoon) is trained in counseling and has experience in therapeutic interaction. The PI has training and previous work experience in clinical social work and will be available to all participants via cell phone, email, or in person when she is at Fort Peck to address any concerns regarding the data collection instruments. The remaining staff will receive specialized training in sexual and reproductive health and will also be available to participants.

G. Dissatisfaction Safeguards: Participants will be encouraged to discuss with the PI or Fort Peck-based project personnel any possible dissatisfaction with the data collection tools or intervention activities.

3. Response Procedures for Adverse Events

A. Discomfort with Disclosure: All project personnel working in the reservation communities are under the supervision of the PI, who is highly trained in counseling. Any participant experiencing embarrassment or discomfort when completing data collection tools will be responded to in a compassionate and professional manner. If a participant experiences any other adverse reactions to the data collection tools or intervention activities/sessions, the participant will be referred to IHS Poplar Service Unit, HIS Wolf Point Service Unit, or the Fort Peck Tribes Health Promotion and Disease Prevention Program (HPDP) on the Fort Peck reservation, which all have trained psychotherapists available to tribal members. Participants will also be encouraged to contact the research team/project personnel in the event of a late adverse reaction and will receive specific written and verbal instructions during the project consent procedures about how to do so if the need arises.

B. Mandatory Reporting: Serious adversities shared by subjects that need to be reported by the research team/project personnel include physical abuse and neglect or threat of physical harm to self or others. To anticipate these concerns, the research team/project personnel have established procedures and guidelines to respond to risk disclosures among participants.

Four types of situations require special procedures:

- Suicide thoughts or attempts: Two types of risks will be addressed in the project: (a) ideation or presentation of thoughts or interest in suicide, and (b) action, which includes both thoughts of suicide as well as the presence of a plan and means to accomplish a suicide act. As participants complete the data collection instruments, key personnel will review instruments and items for response values that indicate concern. Based on the response values, these key personnel will collectively review disclosed information and, if deemed necessary, conduct follow-up inquiry with the participant to further determine level of risk. If the participant is determined to present immediate risk, a referral will be made to one of the following, depending on which is most appropriate for the situation: IHS Poplar Service Unit, IHS Wolf Point Service Unit, or Fort Peck Tribes' Health Promotion and Disease Prevention Program, which offers mental health services to youth in schools. If the disclosure is the result of one of the written items on the data collection tools, Ms. FireMoon will contact the participant by telephone. If the disclosure occurs during an on-site session, the session leader will follow through with an in-depth interview to clarify the presence of suicidal risk and develop a plan of action. Session leaders and mentors will be trained and required to identify suicidal risks in both the domains of ideation and action. Session leaders will follow up in the same way and inform the PI. In the most extreme cases of risk, the PI then assumes follow-up responsibility for the plan of action.
- Abuse: Child abuse concerns may arise from any or a combination of the following sources: (a) the youth verbally indicates that abuse has occurred or is occurring; (b) the youth answers one or more data collection tool items suggesting the possibility of abuse; (c) the youth is observed being treated in an abusive manner; (d) the youth is observed with bodily injury (e.g., bruise, burns, black eyes) whose origin appears to differ from the explanation given of the injury. At any time during the completion of the data collection instruments, or during intervention sessions, if any of the above information leads key personnel or mentors to suspect abuse or neglect of children, documented steps will be followed to obtain additional information and personnel will contact the PI. Based on the information, the team will determine appropriate further inquiry and follow-up. Based on the information, the team will develop a safety plan that may include a participatory report to the Fort Peck Tribes/BIA Child Protective Services

agency, and/or possible referral to the Fort Peck Tribes' Family Violence Resource Center based in Wolf Point.

- **Threat of danger to others:** The threat of danger to others includes disclosure of potential physical harm by a participant to others, including members of the participant's family or other individuals in the school or community. At any time during completion of data collection tools or during intervention sessions, if any information emerges suggesting the threat of harm to others, the team will review the information and determine next steps in accordance with the law, school policies, and the guidance of the CAB and project partners.
- **Addiction:** Addiction to substances is a condition characterized by compulsive substance intake, craving, and seeking, despite negative consequences associated with the substance(s) used. This project does not directly address substance abuse and addiction. However, the student survey asks about substance use, and some intervention sessions related to substance use occur outside of school settings. A situation may occur where a participant reveals information or exhibits characteristics that suggest addiction to substances. The key personnel and mentors will be trained to recognize signs and symptoms of addiction. Together with the PI they will determine the best response and plan for referral to Spotted Bull Addiction Services based in Poplar on the reservation.

C. SRH Health Risks and Needs: Due to the intervention and research subject matter of sexual and reproductive health, participants may reveal information during data collection or intervention sessions that suggests either sexually transmitted infections, HIV, HCV, or suspected pregnancy. Key personnel and mentors will have received training on the services available through the local IHS Service Units to test and treat STIs, HIV, HCV, and/or to provide pregnancy testing and prenatal care. Participants who present these issues will be referred to the appropriate health practitioners for care, and project personnel will follow up with participants as needed to ensure action was taken to address health risks. The intervention program itself will encourage youth to access services for disease and pregnancy prevention.

D. Reporting Procedures for Adverse Events

The anticipated potential adversity inherent in the completion of the student survey is limited and will be addressed by the timely intervention of the key personnel and mentors, as appropriate-all with prior skills and/or training in risk assessment and mandatory reporting requirements. The occurrence of adverse events will be reported to the MSU and Fort Peck IRBs, the Data and Safety Monitoring Committee, and others as appropriate including the participating schools.

E. Reporting Procedure for Serious Unanticipated Adverse Events: In the event of an unanticipated serious adverse event, the PI and Project Director will ensure that these events are reported to the NIH Program Official within hours by phone, fax, and/or email and will submit a written report to the Program Official no more than two days later. Project personnel will also utilize the following reporting procedures:

- 1) When the research team/project personnel become aware of a serious adverse event, reporting requirements must be implemented in a timely manner.
- 2) The PI completes an Adverse Event Report and submits it to the MSU and Fort Peck IRB Chairs, to the project's Data and Safety Monitoring Committee, and to the project Community Advisory Board. The CAB will help identify culturally and socially appropriate ways of remedying adverse events.
- 3) The Chairs will convene expedited meetings of their respective IRBs. First the Fort Peck IRB and then the MSU IRB, with input from the PI and the Data and Safety Monitoring Committee, will review the study protocol and determine what further action to take based on the best interests of the participants and of the research.

F. Oversight

The boards that provide oversight to *NIE* are:

- Community Advisory Board
- The Fort Peck Institutional Review Board
- The Fort Peck Tribal Executive Board
- Montana State University Office of Research Compliance
- Montana State University Office of Sponsored Programs
- The Montana State University Institutional Review Board
- Data Safety and Monitoring Board

For the purposes of the Data Safety and Monitoring Plan, the Data Safety and Monitoring Board (DSMB) will be chaired by Dr. Jared Jobe, retired NIH program officer, Dr. David Huh, a researcher and statistician, Dr. William Lambert, a researcher, and Dr. Cynthia Pearson, a researcher. Meetings of the Committee will occur semi-annually by telephone or Zoom, and unless closed by the Chair, will be joined by the PI (Rink), the Project Director (Paula FireMoon), Ramey Growing Thunder, the Director of the Fort Peck Tribes Language and Culture Program, the study statistician (Mike Anastario), Dr. Julie Baldwin, the study co-Investigator, and the study's research program manager (Genevieve Cox). The DSMB will: a) review the research protocol and plans for data and safety monitoring; b) evaluate study progress, including data quality, participant recruitment rates, retention rates, outcome and adverse experience data, and risk versus benefit profile; and c) review the protocols to protect the confidentiality of the study data and the results of monitoring.

The study's community advisory board is updated quarterly on the study progress. The Fort Peck Tribal Executive Board, the Fort Peck IRS, the MSU IRB, and MSU's Office of Research Compliance and MSU's Office of Sponsored Programs are updated once a year on the study. The DSMB committee also will annually review the project's Data and Safety Monitoring Plan regarding: a) Reassessment of the risks and benefits to study participants; b) Participant recruitment, accrual, and retention; c) Data quality and confidentiality; d) Consideration of external scientific or therapeutic developments with impact on the safety of participants or the ethics of the study; e) Any adverse events.

The research team will update the general Data and Safety Monitoring Plan as well as the research protocols as needed. Adverse events will be reported to the Tribes, the participating schools, and the IRBs on an annual basis. Serious adverse events will be reported immediately to these entities as well as NIH and the DSMB. A written report will follow within 3 days of the event. The written report will be in the format required by the Tribes, schools, and the IRBs, and will contain information regarding the date of the event, description of the event, assessment of cause, whether the event indicates an increased risk for current or future subjects, and whether changes to the informed consent are necessary.

SECTION 8: APPENDICES

The Appendices includes the following documents:

- IRB Approvals
-



Fort Peck Tribal Institutional Review Board
For the Protection of Human Subjects
FWA00019355

Fort Peck Community College
Box 398
Poplar, MT 59255
406-768-5555

Chair: Robert McAnally
406-768-8377
bmcassin@gmail.com

Administrator: Joy Toavs
406-768-5555
itoavs@fpcc.edu



MEMORANDUM

TO: Elizabeth Rink, PhD. MSW

FROM: Robert McAnally —
Chair, Institutional Review Board for the Protection of Human Subjects

DATE: October 26, 2018

SUBJECT: *Nen UnkUmbi/EdaHiYedo* ("We Are Here Now")

The above proposal was reviewed on October 4, 2018 by the Fort Peck Tribal Institutional Review Board. This proposal is now approved for a period of one-year.

Please keep track of the number of subjects who participate in the study and of any unexpected or adverse consequences of the research. If there are any adverse consequences, please report them to the committee as soon as possible. If there are serious adverse consequences, please suspend the research until the situation has been reviewed by the Institutional Review Board.

Any changes in the human subjects' aspects of the research should be approved by the committee before they are implemented.

It is the investigator's responsibility to inform subjects about the risks and benefits of the research. Although the subject's signing of the consent form, documents this process, you, as the investigator should be sure that the subject understands it. Please remember that subjects should receive a copy of the consent form and that you should keep a signed copy for your records.

In one year, you will be sent a questionnaire asking for information about the progress of the research. The information that you provide will be used to determine whether the committee will give continuing approval for another year. If the research is still in progress in 5 years, a complete new application will be required.

The Fort Peck IRB requests that when you have a manuscript, thesis, or presentation prepared for public consumption, that you provide the Fort Peck IRB with an opportunity to review the document prior to publication and to make recommendations to ensure that the document appropriately respects the Fort Peck peoples.



INSTITUTIONAL REVIEW BOARD

For the Protection of Human Subjects
FWA 00000165

960 Technology Blvd. Room 127
c/ o Microbiology & Immunology
Montana State University
Bozeman, MT 59718
Telephone: 406-994-6783
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Chair: Mark Quinn
406-994-4707
mquinn@montana.edu
Administrator:
Cheryl Johnson
406-994-4706
cherylj@montana.edu

MEMORANDUM

TO: Elizabeth Rink

FROM: Mark Quinn
Chair, Institutional Review Board for the Protection of Human Subjects

DATE: February 5, 2018

SUBJECT: *"Nen Onk?umbi/Edahiyedo ('We Are Here Now') - a Multi-level, Multi-component sexual and Reproductive Health Intervention for American Indian Youth" [ER020518]*

The above proposal was reviewed by expedited review by the Institutional Review Board. This proposal is now approved for a period of one-year.

Please keep track of the number of subjects who participate in the study and of any unexpected or adverse consequences of the research. If there are any adverse consequences, please report them to the committee as soon as possible. If there are serious adverse consequences, please suspend the research until the situation has been reviewed by the Institutional Review Board.

Any changes in the human subjects' aspects of the research should be approved by the committee before they are implemented.

It is the investigator's responsibility to inform subjects about the risks and benefits of the research. Although the subject's signing of the consent form, documents this process, you, as the investigator should be sure that the subject understands it. Please remember that subjects should receive a copy of the consent form and that you should keep a signed copy for your records.

In one year, you will be sent a questionnaire asking for information about the progress of the research. The information that you provide will be used to determine whether the committee will give continuing approval for another year. If the research is still in progress in 5 **years**, a complete new application will be required.

Nen OnkUmbi/EdaHiYedo ("We Are Here Now")
**Informed Consent to Participate in Human Subjects Research with Montana State University in
Partnership with Fort Peck Community College**

What is this project about?

We Are Here Now is an intervention project with Fort Peck Community College and Montana State University. The purpose of this intervention is to teach youth at Fort Peck important things they need to know about sex so that they can stay healthy and not get a sexually transmitted disease, HIV, or Hepatitis C, and so that they can make healthy decisions about having children, getting pregnant, or getting someone pregnant. *We Are Here Now* teaches parents about how to speak with their child about sensitive topics related to sex. *We Are Here Now* also teaches Assiniboiné and Sioux youth about their culture and traditional beliefs and practices about what it means to be a young Native person who will soon be an adult.

Why me?

You have been selected to participate in this focus group because you participated in *We Are Here Now*. You may choose to participate or not participate in this focus group at any time.

What happens to me if I decide to participate?

If you decide to be in this focus group we will be asking you questions about what you liked and did not like about *We Are Here Now*. The focus group will be about 1 hour. We will ask you questions about what you thought was good about *We Are Here Now* and what you did not like so much. We will also ask you what you think we need to change to make the program better the next time we do the program here at Fort Peck. We will record the focus group and we will not keep track of who is saying what. This means that nothing you say will be associated with you. Your responses are anonymous. If you agree to participate in this focus group, you will receive a \$10 gift card that you can use here at Fort Peck.

What are the risks?

There may be very minimal risks to participating in the focus group. We are going to ask you questions about what you liked and did not like about *We Are Here Now*. Maybe you might feel uncomfortable sharing with us what you thought about the program. That is okay. It is important that we hear for you about what you liked and did not like about *We Are Here Now* so that we can make it better the next time we implement the program here. If there is something you would really like us to know and do not feel comfortable talking about it in the focus group you can contact Paula Firemoon at Fort Peck Community College and speak with her.

What are the benefits?

The information gathered in this focus group will help the *We Are Here Now*'s research team and members of the Fort Peck community to understand how to make this program better for young people on the reservation.

Who gets access to information from this interview?

The research team has access to the data collected for this project. The *We Are Here Now* community advisory board will also have access to the data collected for this intervention. All responses in this focus group are confidential amongst the other people in the focus group. It is important that what we say in the focus group stays here. So that we respect what everyone has to say. In the transcripts created from the focus group recording none of the responses will be associated with your name. This means that your responses in the focus group transcripts are anonymous. Neither the research team nor the community advisory board will know who you are in the focus group transcripts.

MSU IRB
02/05/2018
Date approved

How am I informed about the results of the project, and when will they be released and presented to someone else?

We will publish the intervention results and make presentations on the results from *We Are Here Now*. Your identity will never appear in a publication or in print or be discussed at a presentation. In addition, you will have the opportunity to learn about the intervention results by contacting members of the research team, attending community meetings where we share the results of the project, and through local (Fort Peck Reservation) media.

Who is involved in We Are Here Now?

If you have any questions regarding this survey please contact:

Paula Firemoon, Fort Peck Community College - Email: PFiremoon@fpcc.edu ; Phone: 406.768.6300

Ramey Growing Thunder, Fort Peck Tribes Language and Culture Department

Email:rgrowingthunder@gmail.com; Phone: 406.768-3520

Elizabeth Rink, Montana State University- Email: elizabeth.rink@montana.edu; Phone: 406.994.3833

CONSENT STATEMENT

If the research participant is a minor:

If you are 18 years or younger and you agree to participate in this focus group, please read, complete, and sign the statement below. By signing this consent form you are giving your verbal and written consent to complete this focus group.

Minor: I have read the above and understand the discomfort, inconvenience, and risks associated with this focus group.

I, _____, **agree** to participate in this focus group.

Name of Minor

Minor Participant Signature: _ _ _ _ _ *Date:* _____

Parent/Legal Guardian agreement for minor:

If as a parent or guardian you **do want** your child to participate in this focus group, please read, complete, and sign the statement below.

Parent/Legal Guardian for Minor: I have read the above and understand the discomfort, inconvenience, and risks associated with this focus group.

I, _____, **do agree** to have my child participate in this focus group.

Name of Parent/Guardian: _____ *Date:* _____

Parent/Guardian Signature: _____ *Date:* _____

Focus Group Administrator Signature: _____ *Date:* _____

APPROVED
MSU IRB
10/03/2018
Date approved

Nen OnkUmbi/EdaHiYedo ("We Are Here Now")
**Informed Consent to Participate in Human Subjects Research with Montana State
University in Partnership with Fort Peck Community College**

What is this project about?

We Are Here Now is an intervention project with Fort Peck Community College and Montana State University. The purpose of this intervention is to teach youth at Fort Peck important things they need to know about sex so that they can stay healthy and not get a sexually transmitted disease, HIV, or Hepatitis C, and so that they can make healthy decisions about having children, getting pregnant, or getting someone pregnant. *We Are Here Now* teaches parents about how to speak with their child about sensitive topics related to sex. *We Are Here Now* also teaches Assiniboine and Sioux youth about their culture and traditional beliefs and practices about what it means to be a young Native person who will soon be an adult.

Why me?

You have been selected to participate in this focus group because you participated in *Native Voices* which is part of a larger intervention called *We Are Here Now*. You may choose to participate or not participate in this focus group at any time.

What happens to me if I decide to participate?

If you decide to be in this focus group we will be asking you questions about what you liked and did not like about *Native Voices*. The focus group will be about 1 hour. We will ask you questions about what you thought was good about *Native Voices* and what you did not like so much. We will also ask you what you think we need to change to make the program better the next time we do the program here at Fort Peck. We will record the focus group and we will not keep track of who is saying what. This means that nothing you say will be associated with you. Your responses are anonymous. If you agree to participate in this focus group, you will receive a \$20 gift card that you can use here at Fort Peck.

What are the risks?

There may be very minimal risks to participating in the focus group. We are going to ask you questions about what you liked and did not like about *Native Voices*. Maybe you might feel uncomfortable sharing with us what you thought about the program. That is okay. It is important that we hear for you about what you liked and did not like about *Native Voices* so that we can make it better the next time we implement the program here. We will also ask you questions about what you may have changed about the what and how you speak with your child about sex or relationships as a result of participating in *Native Voices*. If there is something you would really like us to know and do not feel comfortable talking about it in the focus group you can contact Paula Firemoon at Fort Peck Community College and speak with her.

What are the benefits?

The information gathered in this focus group will help the *We Are Here Now's* research team and members of the Fort Peck community to understand how to make this program better for young people and their parents and families on the reservation.

APPROVED
MSU IRB
10/03/2018
Date approved

Who gets access to information from this interview?

The research team has access to the data collected for this project. The *We Are Here Now* community advisory board will also have access to the data collected for this intervention. All responses in this focus group are confidential amongst the other people in the focus group. It is important that what we say in the focus group stays here. So that we respect what everyone has to say. In the transcripts created from the focus group recording none of the responses will be associated with your name. This means that your responses in the focus group transcripts are anonymous. Neither the research team nor the community advisory board will know who you are in the focus group transcripts.

How am I informed about the results of the project, and when will they be released and presented to someone else?

We will publish the intervention results and make presentations on the results from *We Are Here Now*. Your identity will never appear in a publication or in print or be discussed at a presentation. In addition, you will have the opportunity to learn about the intervention results by contacting members of the research team, attending community meetings where we share the results of the project, and through local (Fort Peck Reservation) media.

Who is involved in *We Are Here Now*?

If you have any questions regarding this focus group please contact:

Paula Firemoon, Fort Peck Community College

Email: PFiremoon@fpcc.edu; Phone: 406.768.6300

Ramey Growing Thunder, Fort Peck Tribes Language and Culture Department

Email: rgrowingthunder@gmail.com; Phone: 406.768-3520

Elizabeth Rink, Montana State University

Email: elizabeth.rink@montana.edu; Phone: 406.994.3833

CONSENT STATEMENT

Parent/Legal Guardian: I have read the above and understand the discomfort, inconvenience, and risks associated with this focus group.

I, _____, **do agree** to participate in this focus group.

Name of Parent/Guardian: _____

Parent/Guardian Signature: _____ *Date:* _____

Focus Group Administrator Signature: _____ *Date:* _____

INSTITUTIONAL REVIEW BOARD

For the Protection of Human Subjects
FWA 00000165



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MEMORANDUM

TO: Elizabeth Rink, Genevieve Cox, Paula Firemoon, Mike Anastario

FROM: Mark Quinn
Chair, Institutional Review Board for the Protection of Human Subjects

DATE: October 3, 2018

SUBJECT: "Nen unk?umbi/Edahiyedo ("We Are Here Now"? - a Multi-level, Mu/ti-component Sexual and Reproductive Health Intervention for American Indian Youth" [ER100318-FC]

The above proposal was reviewed by the Institutional Review Board. This proposal is now approved for a period of one-year.

Please keep track of the number of subjects who participate in the study and of any unexpected or adverse consequences of the research. *If there are any adverse consequences, please report them to the committee within 3 calendar days.* If there are serious adverse consequences, please suspend the research until the situation has been reviewed by the Institutional Review Board.

Any changes in the human subjects' aspects of the research should be approved by the committee before they are implemented.

It is the investigator's responsibility to inform subjects about the risks and benefits of the research. Although the subject's signing of the consent form, documents this process, you, as the investigator should be sure that the subject understands it. Please remember that subjects should receive a copy of the consent form and that you should keep a signed copy for your records.

In one year, you will be sent a questionnaire asking for information about the progress of the research. The information that you provide will be used to determine whether the committee will give continuing approval for another year. If the research is still in progress in 5 years, a complete new application will be required.

***NenUnkUmbi/EdaHiYedo* ("We Are Here Now")**

Waiver of Consent to Participate in Human Subjects Research with Montana State University in Partnership with Fort Peck Community College

We Are Here Now is an intervention project with Fort Peck Community College and Montana State University. ***NenUnkUmbi/EdaHiYedo* ("We are Here Now," or *NIE*)** derives from the Assiniboiné (*NenUnkUmbi*) and Sioux (*EdaHiYedo*) names for their traditional coming-of-age ceremonies. The purpose of this program is to teach youth at Fort Peck important things they need to know about sex so that they can stay healthy and not get a sexually transmitted disease, HIV, or Hepatitis C, and so that they can make healthy decisions about having children, getting pregnant, or getting someone pregnant. *We Are Here Now* also includes tribal elders and leaders teaching Assiniboiné and Sioux youth about their culture and traditional beliefs and practices about what it means to be a young Native person who will soon be an adult. In addition to working with youth, *We Are Here Now* also is offering education to parents/legal guardians about how to speak with their children about sensitive topics related to sex.

As part of N/E will be working with the Fort Peck Epi Team to evaluate the reproductive health services available to youth on the Fort Peck Indian Reservation. Members of the Montana State University and Fort Peck based research team will be attending Epi team meetings to assess the reproductive health services available for youth on the reservation. These meetings will include discussions of the barriers and facilitators of reproductive health and tracking any changes that the agency you work for makes as result of our discussions. The Montana State University and Fort Peck based research team will provide regular feedback to the Epi Team of the monitoring we are conducting related to the barriers and facilitators of reproductive health services for tribal youth.

Our discussions will be audiotaped and transcribed in order to conduct content analysis of the primary themes that emerge related to the barriers and facilitators of our discussions. There is no risk associated with your involvement in the discussions; and there is no cost or compensation to you for participation in our discussions.

If you have any questions regarding N/E please contact:

Paula FireMoon, Fort Peck Community College

Email: PFiremoon@fpcc.edu; Phone: 406.768.6300

Elizabeth Rink, Montana State University

Email: elizabeth.rink@montana.edu; Phone: 406.994.3833

Mark Quinn, Montana State University Institutional Review Board Chair

Email: mguinn@montana.edu; Phone: 406.994.4707

CONSENT STATEMENT

I have read the purpose of N/E and the role of the Epi Team in this study.

I, _____, **do agree** to participate in the Epi Team discussions related to assessing the barriers and facilitators of reproductive health services of youth on the Fort Peck Indian Reservation.

Signature: _____ Date: _____

APPROVED
MSU IRB
10/03/2018
Date approved

NenUnkUmbi/EdaHiYedo ("We Are Here Now")
**Informed Consent to Participate in Human Subjects Research with Montana State University in
Partnership with Fort Peck Community College**

What is this project about?

We Are Here Now is an intervention project with Fort Peck Community College and Montana State University. The purpose of this intervention is to teach youth at Fort Peck important things they need to know about sex so that they can stay healthy and not get a sexually transmitted disease, HIV, or Hepatitis C, and so that they can make healthy decisions about having children, getting pregnant, or getting someone pregnant. *We Are Here Now* also teaches Assiniboiné and Sioux youth about their culture and traditional beliefs and practices about what it means to be a young Native person who will soon be an adult.

Why me?

You have been selected to participate in *We Are Here Now* because you are a young person at Fort Peck. You may choose to participate or not participate at any time.

What happens to me if I decide to participate?

If you decide to be in *We Are Here Now*, you will participate in a survey that will take 50 to 60 minutes. You will be asked to complete this survey three more times during the next year so that we can keep track of any changes you may have in your beliefs and behaviors as a result of participating in *We Are Here Now*. You will be asked several questions about different topics related to sex, having children, and sexually transmitted diseases in order to learn about what you think about having children and what you know about sexually transmitted diseases. You will also be asked questions about your sexual behavior and experiences with drugs and alcohol. You will also be asked questions about your feelings and emotions and your traditional culture. It is important that you know that all of your responses on this survey are anonymous. This means that no one will know that it is you who answered these questions. Your responses will be kept track of in the computer that you are taking the survey on. Your name will be nowhere in the computer or on the survey. There is no cost to you if you agree to participate in this study. If you agree to participate in this survey, you will receive a \$10 gift card that you can use here at Fort Peck. Also by agreeing to participate in *We Are Here Now*, your parent/legal guardian is agreeing to participate in an educational program called *Native Voices*, and you are agreeing to be part of a cultural mentoring program with the Fort Peck Tribes' Language and Culture Department.

What are the risks?

There may be minor risks to agreeing to participate in the survey. Some of the questions may make you feel uncomfortable, sad, or confused. You may choose to stop the survey at any time or decline to answer a particular question. The questions will be about your life experiences as they relate to sex, drug and alcohol use, having children, sexually transmitted diseases, your feelings and emotions, and your understanding of your traditional culture. A list of resources are provided in this consent form if you feel that you would like to speak with someone further about your life experiences. None of the things that you say on the survey will be connected to your name.

What are the benefits?

The information gathered in this survey will help the intervention's research team and members of the Fort Peck community to understand what kind of impact your participation in *We Are Here Now* is having on your decisions to avoid getting a sexually transmitted disease and your decisions about having children when you feel you are ready. We would also like you to know that if you tell us about any abusive situation you are experiencing or have experienced, we will need to report that to the appropriate services here at Fort Peck so that you can receive assistance.

Who gets access to information from this interview?

All responses on this survey will be confidential. Only one person, Paula FireMoon, will know that you participated. Your personal information such as your name, telephone number and address will be linked to a study identification number to track your participation in the study. Your personal information will only be kept in order to contact you to participate in the follow up data collection for this study. Your personal information will be kept in a locked file cabinet at the Fort Peck Community College Institutional Review Board administration office in Poplar. Neither Paula nor the rest of the research team, nor the community advisory

board, will know what your individual responses to the survey are. The data collected in this study will not be associated with your name. The research team and the community advisory board will have access to the data collected for this project with no identifying information on it that can be associated with your name.

How am I informed about the results of the project, and when will they be released and presented to someone else?

We will publish the intervention results and make presentations on the results from *We Are Here Now*. Your identity will never appear in a publication or in print or be discussed at a presentation. In addition, you will have the opportunity to learn about the intervention results by contacting members of the research team, attending community meetings where we share the results of the project, and through local (Fort Peck Reservation) media.

Who is involved in *We Are Here Now*?

If you have any questions regarding this survey please contact:

Paula FireMoon, Fort Peck Community College

Email: PFiremoon@fpcc.edu; Phone: 406.768.6300

Elizabeth Rink, Montana State University

Email: elizabeth.rink@montana.edu; Phone: 406.994.3833

Mark Quinn, Montana State University Institutional Review Board Chair

Email: mquinn@montana.edu; Phone: 406.994. 4707

CONSENT STATEMENT

If the research participant is a minor:

If you are 18 years or younger and you agree to participate in this survey, please read, complete, and sign the statement below. By signing this consent form you are giving your verbal and written consent to complete this survey.

Minor: I have read the above and understand the discomfort, inconvenience, and risks associated with this survey.

I, _____, **agree** to participate in this survey.

Name of Minor

Minor Participant Signature: _____ *Date:* _____

Parent/Legal Guardian agreement for minor:

If as a parent or guardian you **do want** your child to participate in this survey, please read, complete, and sign the statement below.

Parent/Legal Guardian for Minor: I have read the above and understand the discomfort, inconvenience, and risks associated with this survey.

I, _____, **do agree** to have my child participate in this survey.

Name of Parent/Guardian

Parent/Guardian Signature: _____ *Date:* _____

Survey Administrator Signature: _____ *Date:* _____

APPROVED
MSU IRB
10/03/2018
Date approved

***NenUnkUmbi/EdaHiYedo* ("We Are Here Now")**
Informed Consent to Participate in Human Subjects Research with Montana State University in Partnership with Fort Peck Community College

What is this project about?

We Are Here Now is an intervention project with Fort Peck Community College and Montana State University. ***NenUnkUmbi/EdaHiYedo* ("We are Here Now," or NIE)** derives from the Assiniboiné (*NenUnkUmbi*) and Sioux (*EdaHiYedo*) names for their traditional coming-of-age ceremonies. The purpose of this program is to teach youth at Fort Peck important things they need to know about sex so that they can stay healthy and not get a sexually transmitted disease, HIV, or Hepatitis C, and so that they can make healthy decisions about having children, getting pregnant, or getting someone pregnant. *We Are Here Now* also includes tribal elders and leaders teaching Assiniboiné and Sioux youth about their culture and traditional beliefs and practices about what it means to be a young Native person who will soon be an adult. In addition to working with youth, *We Are Here Now* also is offering education to parents/legal guardians about how to speak with their children about sensitive topics related to sex.

Why me?

You and your child have been invited to participate in *We Are Here Now* and to help gather information about the program and its effects. Your participation in this intervention is entirely voluntary. You can choose not to participate at any time. You and your child may withdraw from the intervention at any time without negative consequences. Your participation in *We Are Here Now* is your choice.

What happens to me if I decide to participate?

If you agree to participate in *We Are Here Now*, you will be with other guardians or parents of young people who are participating in *We Are Here Now*, and you will learn about how to talk with your child about sex. *We Are Here Now* is a project that educates youth and their guardians/parents about sexual and reproductive health. As a participant in *We Are Here Now*, you will be talking with other guardians/parents about healthy sexual behaviors and about how to talk with your children about sex. You will be asked to complete a survey specifically for guardians/parents about how you talk to your child about sex and what kinds of things about sex you speak with them about. There is no cost to you if you agree to participate in this study. You will receive an incentive of \$20 for this first survey, and then \$10 each time you attend the four *Native Voices* sessions (at 2 of these sessions you will again fill out the survey). Finally, you will receive a \$25 incentive for completing the final survey after the end of the program.

What are the risks?

Some of the questions may make you feel a bit uncomfortable. For example, we will ask you about what kinds of sexual topics you talk about with your child. A list of community resources is provided with this informed consent if you feel you would like to speak with someone further about feelings that may have been brought up as a result of your participation in this study.

What are the benefits?

Through this program you will learn about ways to speak effectively with your child about sex and topics related to sexual health. The information gathered in this survey will help the intervention's research team and members of the Fort Peck community to understand what kind of impact your participation in *We Are Here Now* is having on your decisions to talk with your child about sensitive

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10/03/2018
Date approved

topics related to sex.

Who gets access to information from this interview?

All responses on this survey will be confidential. Only one person, Paula FireMoon, will know that you participated. Your personal information such as your name, telephone number and address will be linked to a study identification number to track your participation in the study. Your personal information will only be kept in order to contact you to participate in the follow up data collection for this study. Your personal information will be kept in a locked file cabinet at the Fort Peck Community College Institutional Review Board administration office in Poplar. Neither Paula nor the rest of the research team, nor the community advisory board, will know what your individual responses to the survey are. The data collected in this study will not be associated with your name. The research team and the community advisory board will have access to the data collected for this project with no identifying information on it that can be associated with your name.

How am I informed about the results of the project, and when will they be released and presented to someone else?

We will publish the intervention results and make presentations on the results from *We Are Here Now*. Your identity will never appear in a publication or in print or be discussed at a presentation. In addition, you will have the opportunity to learn about the intervention results by contacting members of the research team, by attending community meetings where we share the results of the project, and through local (Fort Peck Reservation) media.

Who is involved in *We Are Here Now*?

If you have any questions regarding this survey please contact:

Paula FireMoon, Fort Peck Community College

Email: PFiremoon@fpcc.edu; Phone: 406.768.6300

Elizabeth Rink, Montana State University

Email: elizabeth.rink@montana.edu; Phone: 406.994.3833

Mark Quinn, Montana State University Institutional Review Board Chair

Email: mquinn@montana.edu; Phone: 406.994. 4707

CONSENT STATEMENT

Parent/Legal Guardian for Minor: I have read the above and understand the discomfort, inconvenience, and risks associated with this survey.

I, _____, **do agree** to participate in this survey.
Name of Parent/Guardian

Parent/Guardian Signature: _____ *Date:* _____

Survey Administrator Signature: _____ *Date:* _____

APPROVED
MSU IRB
10/03/2018
Date approved



INSTITUTIONAL REVIEW BOARD

For the Protection of Human Subjects

FWA 00000165

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Chair: Mark Quinn
406-994-4707
mquinn@montana.edu
Administrator:
Cheryl Johnson
406-994-4706
cherylj@montana.edu

MEMORANDUM

TO: Elizabeth Rink

FROM: Mark Quinn
Chair, Institutional Review Board for the Protection of Human Subjects

DATE: August 9, 2019

SUBJECT: *"Nen Onk?umbi/Edahiyedo ('We Are Here Now') - a Multi-level, Multi-component sexual and Reproductive Health Intervention for American Indian Youth - Pilot Study [ER020518]*

This is to acknowledge receipt of the request dated August 8, 2019 for a minor modification to the above protocol. The request for the following modification is approved:

- Increase the incentive for parents to complete the final survey three months after finishing Native Voices.

***NenUnkUmbi/EdaHiYedo* ("We Are Here Now")**
Informed Consent to Participate in Human Subjects Research with Montana State University in Partnership with Fort Peck Community College

What is this project about?

We Are Here Now is an intervention project with Fort Peck Community College and Montana State University. ***NenUnkUmbi/EdaHiYedo* ("We are Here Now," or *NIE*)** derives from the Assiniboine (*NenUnkUmb1*) and Sioux (*EdaHiYedo*) names for their traditional coming-of-age ceremonies. The purpose of this program is to teach youth at Fort Peck important things they need to know about sex so that they can stay healthy and not get a sexually transmitted disease, HIV, or Hepatitis C, and so that they can make healthy decisions about having children, getting pregnant, or getting someone pregnant. *We Are Here Now* also includes tribal elders and leaders teaching Assiniboine and Sioux youth about their culture and traditional beliefs and practices about what it means to be a young Native person who will soon be an adult. In addition to working with youth, *We Are Here Now* also is offering education to parents/legal guardians about how to speak with their children about sensitive topics related to sex.

Why me?

You and your child have been invited to participate in *We Are Here Now* and to help gather information about the program and its effects. Your participation in this intervention is entirely voluntary. You can choose not to participate at any time. You and your child may withdraw from the intervention at any time without negative consequences. Your participation in *We Are Here Now* is your choice.

What happens to me if I decide to participate?

If you agree to participate in *We Are Here Now*, you will be with other guardians or parents of young people who are participating in *We Are Here Now*, and you will learn about how to talk with your child about sex. *We Are Here Now* is a project that educates youth and their guardians/parents about sexual and reproductive health. As a participant in *We Are Here Now*, you will be talking with other guardians/parents about healthy sexual behaviors and about how to talk with your children about sex. You will be asked to complete a survey specifically for guardians/parents about how you talk to your child about sex and what kinds of things about sex you speak with them about. There is no cost to you if you agree to participate in this study. You will receive an incentive of \$20 each time you attend the four *Native Voices* sessions. At 2 of these sessions you will fill out a survey. You will also receive a \$25 incentive for completing the final survey three months after finishing *Native Voices*.

What are the risks?

Some of the questions may make you feel a bit uncomfortable. For example, we will ask you about what kinds of sexual topics you talk about with your child.

What are the benefits?

Through this program you will learn about ways to speak effectively with your child about sex and topics related to sexual health. The information gathered in this survey will help the intervention's research team and members of the Fort Peck community to understand what kind of impact your participation in *We Are Here Now* is having on your decisions to talk with your child about sensitive topics related to sex.

APPROVED

08/09/2019
Date approved

Who gets access to information from this interview?

All responses on this survey will be confidential. Only one person, Paula FireMoon, will know that you participated. Your personal information such as your name, telephone number and address will be linked to a study identification number to track your participation in the study. Your personal information will only be kept in order to contact you to participate in the follow up data collection for this study. Your personal information will be kept in a locked file cabinet at the Fort Peck Community College Institutional Review Board administration office in Poplar. Neither Paula nor the rest of the research team, nor the community advisory board, will know what your individual responses to the survey are. The data collected in this study will not be associated with your name. The research team and the community advisory board will have access to the data collected for this project with no identifying information on it that can be associated with your name.

How am I informed about the results of the project, and when will they be released and presented to someone else?

We will publish the intervention results and make presentations on the results from *We Are Here Now*. Your identity will never appear in a publication or in print or be discussed at a presentation. In addition, you will have the opportunity to learn about the intervention results by contacting members of the research team, by attending community meetings where we share the results of the project, and through local (Fort Peck Reservation) media.

Who is involved in We Are Here Now?

If you have any questions regarding this survey please contact:

Paula FireMoon, Fort Peck Community College

Email: PFiremoon@fpcc.edu; Phone: 406.768.6300

Elizabeth Rink, Montana State University

Email: elizabeth.rink@montana.edu; Phone: 406.994.3833

Mark Quinn, Montana State University Institutional Review Board Chair

Email: mquinn@montana.edu; Phone: 406.994.4707

CONSENT STATEMENT

Parent/Legal Guardian for Minor: I have read the above and understand the discomfort, inconvenience, and risks associated with this survey.

I, _____, **do agree** to participate in this survey.

Name of Parent/Guardian

Parent/Guardian Signature: _____ *Date:* _____

Survey Administrator Signature: _____ *Date:* _____

APPROVED

MSU IRB

08/09/2019
Date approved



INSTITUTIONAL REVIEW BOARD
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Chair: Mark Quinn
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Administrator:
Cheryl Johnson
406-994-4706
cherylj@montana.edu

MEMORANDUM

TO: Elizabeth Rink

FROM: Mark Quinn
Chair, Institutional Review Board for the Protection of Human Subjects

DATE: April 20, 2020

SUBJECT: *"Nen Onk?umbi/Edahiyedo ('We Are Here Now'? - a Multi-level, Multi-component Sexual and Reproductive Health Intervention for American Indian Youth- Pilot Study" [ER020518]*

This is to acknowledge receipt of the request dated April 20, 2020 for minor modifications to the above protocol. The request for the following modifications is approved:

- Protocol is being changed for parents to read and complete a parent educational packet of resources alongside one-on-one meetings with our Native implementors, rather than group educational sessions;
- Request to include Focus Groups focused on Fidelity, Acceptability, and Sustainability of the project implementation to be conducted in summer 2020. A total of 8 focus groups will be conducted including two focus groups with youth participants, two focus groups with parents of youth participants, 2 focus groups surrounding the cultural mentoring components of the intervention, and 2 focus groups with professionals involved in the intervention.

***NenUnkUmbi/EdaHiYedo* ("We Are Here Now")**
**Informed Consent to Participate in Human Subjects Research with Montana State University in
Partnership with Fort Peck Community College**

We Are Here Now is an intervention project with Fort Peck Community College and Montana State University. ***NenUnkUmbi/EdaHiYedo* ("We are Here Now," or *NIE*)** derives from the Assiniboiné (*NenUnkUmb1*) and Sioux (*EdaHiYedo*) names for their traditional coming-of-age ceremonies. The purpose of this program is to teach youth at Fort Peck important things they need to know about sex so that they can stay healthy and not get a sexually transmitted disease, HIV, or Hepatitis C, and so that they can make healthy decisions about having children, getting pregnant, or getting someone pregnant. *We Are Here Now* also includes tribal elders and leaders teaching Assiniboiné and Sioux youth about their culture and traditional beliefs and practices about what it means to be a young Native person who will soon be an adult. In addition to working with youth, *We Are Here Now* also is offering education to parents/legal guardians about how to speak with their children about sensitive topics related to sex.

You have been chosen to participate in a Focus Group to help us understand the value and effectiveness of *We Are Here Now* because you are involved in the intervention as a youth participant in the schools, as a parent of a participant, or as someone who has been helping to facilitate *We Are Here Now*. We would like to better understand your point of view on what has worked best so far with *We Are Here Now* and what might be improved. Specifically, we would like to understand what experiences and activities you have liked or did not like, what educational information you liked or did not like, and any recommendations you might have for improving *We Are Here Now*.

Our discussions will be audiotaped and transcribed. These transcriptions are anonymous and confidential, and we will ask all participants to maintain confidentiality of discussions. However, we cannot guarantee full confidentiality because we cannot guarantee that participants involved in this Focus Group will not share stories or discussions outside our group. However, in transcriptions, no names will be used. There is no risk associated with your involvement in the discussions; and there is no cost to you for your participation in our discussions. You will receive \$20 for your time.

We will publish the intervention results and make presentations on the results from *We Are Here Now*. Information from the project **will** also be posted on the U.S. website, <https://ClinicalTrials.gov>. Your identity will never appear in a publication or in print or be discussed at a presentation. In addition, you will have the opportunity to learn about the intervention results by contacting members of the research team, attending community meetings where we share the results of the project, and through your local community media.

If you have any questions regarding this Focus Group please contact:

Paula FireMoon, Fort Peck Community College
Email: PFiremoon@fpcc.edu; Phone: 406-768-6300

Olivia Johnson, Fort Peck Community College
Email: OJohnson@fpcc.edu; Phone: 406-768-6300

Elizabeth Rink, Montana State University
Email: elizabeth.rink@montana.edu; Phone: 406-994-3833

Mark Quinn, Montana State University Institutional Review Board Chair
Email: mquinn@montana.edu; Phone: 406-994-4707

MSU IRB
04/20/2020
Date Approved

CONSENT STATEMENT:

If the research participant is a minor:

If you are 18 years or younger and you agree to participate in this focus group, please read, complete, and sign the statement below. By signing this consent form you are giving your verbal and written consent to complete this focus group.

Minor: I have read the above and understand the discomfort, inconvenience, and risks associated with this focus group.

I, _____, **agree** to participate in this focus group.

Name of Minor

Minor Participant Signature: _ _ _ _ _ *Date:* _ _ _ _ _

Parent/Legal Guardian agreement for minor:

If as a parent or guardian you **do want** your child to participate in this focus group, please read, complete, and sign the statement below.

Parent/Legal Guardian for Minor: I have read the above and understand the discomfort, inconvenience, and risks associated with this focus group.

I, _____, **do agree** to have my child participate in this focus group.

Name of Parent/Guardian: _ _ _ _ _

Parent/Guardian Signature: _ _ _ _ _ *Date:* _ _ _ _ _

Focus Group Administrator Signature: _ _ _ _ _ *Date:* _ _



INSTITUTIONAL REVIEW BOARD
For the Protection of Human Subjects
FWA 00000165

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c/o Microbiology & Immunology
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FAX: 406-994-4303
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Chair: Mark Quinn
406-994-4707
mquinn@montana.edu

Administrator:
Cheryl Johnson
406-994-4706
cherylj@montana.edu

MEMORANDUM

TO: Elizabeth Rink, Genevieve Cox, Paula Firemoon, Mike Anastario

FROM: Mark Quinn
Chair, Institutional Review Board for the Protection of Human Subjects

DATE: September 30, 2020

SUBJECT: *"Nen Onk?umbi/Edahiyedo ("We Are Here Now'J - a Multi-level, Multi-component sexual and Reproductive Health Intervention for American Indian Youth [ER100318-FCJ*

This is to acknowledge receipt of the request dated September 29, 2020 for minor modifications to the above protocol. The request for the following modifications is approved:

- Will conduct a within scope data collection of the impact of COVID-19 on their primary outcome variables and the study's stepped wedge design.
- Will be collecting data from a subset of the study participants. The data collection will include: a chain referral network survey and in-depth interviews.
- Submitted the consent forms and data collection instruments for the two methods of data collection.

Nen OnkUmbi/EdaHiYedo ("We Are Here Now")
**Informed Consent to Participate in Human Subjects Research with Montana State University in
Partnership with Fort Peck Community College**

What is this project about?

We Are Here Now is an intervention project with Fort Peck Community College and Montana State University. The purpose of this intervention is to teach youth at Fort Peck important things they need to know about sex so that they can stay healthy and not get a sexually transmitted disease, HIV, or Hepatitis C, and so that they can make healthy decisions about having children, getting pregnant, or getting someone pregnant. *We Are Here Now* also teaches Assiniboine and Sioux youth about their culture and traditional beliefs and practices about what it means to be a young Native person who will soon be an adult. For the purpose of this interview we would like to learn from you how COVID-19 and the sheltering in place orders have impacted your behaviors.

Why me?

You have been selected to participate in this survey because you participate in the original data collection for *We Are Here Now* in Spring 2019. You may choose to participate or not participate at any time.

What happens to me if I decide to participate?

If you decide to participate in this interview we will ask you a series of questions about how COVID-19 and the sheltering in place orders impacted some of your behaviors and your feelings as well as your friends and family. The interview will take about 45 minutes. You will be asked several questions about different topics related to sex, your feelings and what you did during the sheltering in place orders from March 2020 to May 2020 and then, you will also be asked questions about what has happened in your life more recently. It is important that you know that all of your responses are anonymous. This means that no one will know that it is you who answered these questions. We will audio-tape and transcribe your interview. Your name will be nowhere in the transcript of your interview. If you agree to participate in this interview, you will receive a \$10 gift card that you can use here at Fort Peck. If you would like a copy of your interview please let us know and we will make sure that you receive a copy of the transcript from our discussion.

What are the risks?

There may be minor risks to agreeing to participate in the interview. Some of the questions may make you feel uncomfortable, sad, or confused. You may choose to stop the interview at any time or decline to answer a particular question. The questions will be about your perceptions of what was going on in your life during the sheltering in place orders last Spring, from March 2020 to May 2020 and then now. None of the things that you say in the interview will be connected to your name. Although there are minor risks to agreeing to participate in the interview, if you feel sad or lonely or anxious you can talk to the person here today who is giving you this survey about how you are feeling and they can help you. You are also contact the names on this informed consent and we can assist you with finding someone to help you with how you are feeling.

What are the benefits?

The information gathered in this interview will help us understand how COVID-19 has impacted young people at Fort Peck so that we can help the Tribes, schools and other resources at Fort Peck you and your family now and in the future. We would also like you to know that if you tell us about any abusive situation you are experiencing or have experienced, we will need to report that to the appropriate services here at Fort Peck so that you can receive assistance.

Who gets access to information from this interview?

The research team has access to the data collected for this project. The *We Are Here Now* community advisory board will also have access to the data collected for this intervention. All responses on this survey will be anonymous. Neither the research team nor the community advisory board will know who you are and what your responses to the survey are.

How am I informed about the results of the project, and when will they be released and presented to someone else?

We will publish the results and make presentations on the results from this survey. Your identity will never appear in a publication or in print or be discussed at a presentation. In addition, you will have the opportunity to learn about the intervention results by contacting members of the research team, attending

community meetings where we share the results of the project, and through local (Fort Peck Reservation) media.

Who is involved in We Are Here Now?

If you have any questions regarding this survey please contact:

Paula FireMoon, Fort Peck Community College

Email: PFiremoon@fpcc.edu; Phone: 406.768.6300

Bob McAnnally, Fort Peck Institutional Review Board Chair

Email: bmcassin@gmail.co; Phone: 406.768.6300.

Elizabeth Rink, Montana State University

Email: elizabeth.rink@montana.edu; Phone: 406.994.3833

Mark Quinn, Montana State University Institutional Review Board Chair

Email: MQuinn@montana.edu; Phone: 406-994-4707

CONSENT STATEMENT

If the research participant is a minor:

If you are 18 years or younger and you agree to participate in this survey, please read, complete, and sign the statement below. By signing this consent form you are giving your verbal and written consent to complete this survey.

Minor: I have read the above and understand the discomfort, inconvenience, and risks associated with this survey.

I, _____, **agree** to participate in this survey.

Name of Minor

Minor Participant Signature: _____ Date: _____

Parent/Legal Guardian agreement for minor:

If **as a** parent or guardian you **do want** your child to participate in this survey, please read, complete, and sign the statement below.

Parent/Legal Guardian for Minor: I have read the above and understand the discomfort, inconvenience, and risks associated with this survey.

I, _____ **do agree** to have my child participate in this survey.

Name of Parent/Guardian

Parent/Guardian Signature: _____ Date: _____

Survey Administrator Signature: _____ Date: _____

Nen UnkUmbi/EdaHiYedo ("We Are Here Now")
**Informed Consent to Participate in Human Subjects Research with Montana State University in
Partnership with Fort Peck Community College**

What is this project about?

We Are Here Now is an intervention project with Fort Peck Community College and Montana State University. The purpose of this intervention is to teach youth at Fort Peck important things they need to know about sex so that they can stay healthy and not get a sexually transmitted disease, HIV, or Hepatitis C, and so that they can make healthy decisions about having children, getting pregnant, or getting someone pregnant. *We Are Here Now* also teaches Assiniboiné and Sioux youth about their culture and traditional beliefs and practices about what it means to be a young Native person who will soon be an adult. For the purpose of this survey we would like to learn from you how COVID-19 and the sheltering in place orders have impacted your behaviors.

Why me?

You have been selected to participate in this survey because you participate in the original data collection for *We Are Here Now* in Spring 2019. You may choose to participate or not participate at any time.

What happens to me if I decide to participate?

If you decide to participate in this survey we will ask you a series of questions about how COVID-19 and the sheltering in place orders impacted some of your behaviors and your feelings. The survey that will take about 45 minutes. You will be asked several questions about different topics related to sex, your feelings and what you did during the sheltering in place orders from March 2020 to May 2020 and then, you will also be asked questions about what you have done over the past month. It is important that you know that all of your responses on this survey are anonymous. This means that no one will know that it is you who answered these questions. Your responses will be kept track of in the computer that you are taking the survey on. Your name will be nowhere in the computer or on the survey. If you agree to participate in this survey, you will receive a \$10 gift card that you can use here at Fort Peck. Once you have finished the survey, you will be given a coupon to give to 2 or 3 of the people that you socialize with so that they can participate in the survey also. For each person you tell to participate in the survey you will receive another \$10 gift card. You may also ask you to participate in an interview to talk with us further about what you think is important for us to know about how COVID 19 influenced your life.

What are the risks?

There may be minor risks to agreeing to participate in the survey. Some of the questions may make you feel uncomfortable, sad, or confused. You may choose to stop the survey at any time or decline to answer a particular question. The questions will be about sex, drug and alcohol use, your feelings and emotions, and how your life has been impacted by COVID-19 and the sheltering in place orders. None of the things that you say on the survey will be connected to your name. Although there are minor risks to agreeing to participate in the survey, if you feel sad or lonely or anxious you can talk to the person here today who is giving you this survey about how you are feeling and they are help you. You are also contact the names on this informed consent and we can assist you with finding someone to help you with how you are feeling.

What are the benefits?

The information gathered in this survey will help us understand how COVID-19 has impacted young people at Fort Peck so that we can help the Tribes, schools and other resources at Fort Peck you and your family now and in the future. We would also like you to know that if you tell us about any abusive situation you are experiencing or have experienced, we will need to report that to the appropriate services here at Fort Peck so that you can receive assistance.

Who gets access to information from this interview?

The research team has access to the data collected for this project. The *We Are Here Now* community advisory board will also have access to the data collected for this intervention. All responses on this survey will be anonymous. Neither the research team nor the community advisory board will know who you are and what your responses to the survey are.

APPROVEDMSUIRB

09/30/2020
Date approved

INSTITUTIONAL REVIEW BOARD

How am I informed about the results of the project, and when will they be released and presented to someone else?

We will publish the results and make presentations on the results from this survey. Your identity will never appear in a publication or in print or be discussed at a presentation. In addition, you will have the opportunity to learn about the intervention results by contacting members of the research team, attending community meetings where we share the results of the project, and through local (Fort Peck Reservation) media.

Who is involved in We Are Here Now?

If you have any questions regarding this survey please contact:

Paula FireMoon, Fort Peck Community College

Email: PFiremoon@fpcc.edu; Phone: 406.768.6300

Bob McAnnally, Fort Peck Institutional Review Board Chair

Email: bmcassin@gmail.com; Phone: 406.768.6300.

Elizabeth Rink, Montana State University

Email: elizabeth.rink@montana.edu; Phone: 406.994.3833

Mark Quinn, Montana State University Institutional Review Board Chair

Email: MQuinn@montana.edu; Phone: 406-994-4707

CONSENT STATEMENT

If the research participant is a minor:

If you are 18 years or younger and you agree to participate in this survey, please read, complete, and sign the statement below. By signing this consent form you are giving your verbal and written consent to complete this survey.

Minor: I have read the above and understand the discomfort, inconvenience, and risks associated with this survey.

I, _____, **agree** to participate in this survey.
Name of Minor

Minor Participant Signature: _____ Date: _ _ _ _

Parent/Legal Guardian agreement for minor:

If as a parent or guardian you **do want** your child to participate in this survey, please read, complete, and sign the statement below.

Parent/Legal Guardian for Minor: I have read the above and understand the discomfort, inconvenience, and risks associated with this survey.

I, _____, **do agree** to have my child participate in this survey.
Name of Parent/Guardian

Parent/Guardian Signature: _____ Date: _____

Survey Administrator Signature _____ Date _____

Supplemental Funding Request In-Depth Interview Guide

9-28-20

PI: Elizabeth Lynne Rink, PhD MSW

APPROVED MSU 05/03/2021

IRB# ER

09/30/2020
Date approved

Nen ŪnkŪmbi/EdaHiYedo (“We Are Here Now”)

Informed Consent to Participate in Human Subjects Research with Montana State University in Partnership with Fort Peck Community College

What is this project about?

We Are Here Now is an intervention project with Fort Peck Community College and Montana State University. The purpose of this intervention is to teach youth at Fort Peck important things they need to know about sex so that they can stay healthy and not get a sexually transmitted disease, HIV, or Hepatitis C, and so that they can make healthy decisions about having children, getting pregnant, or getting someone pregnant. *We Are Here Now* also teaches Assiniboiné and Sioux youth about their culture and traditional beliefs and practices about what it means to be a young Native person who will soon be an adult. For the purpose of this interview we would like to learn from you how the COVID-19 pandemic **over the past year** impacted your behaviors.

Why me?

You have been selected to participate in this interview because you participate in the original data collection for *We Are Here Now* in Spring 2019. You may choose to participate or not participate at any time.

What happens to me if I decide to participate?

If you decide to participate in this interview, we will ask you a series of questions about how COVID-19 and the sheltering in place orders impacted some of your behaviors and your feelings as well as your friends and family. The interview that will take about 45 minutes. **You will be asked several questions about different topics related to sex, your feelings and what you did during COVID-19 pandemic when you could not go to school because your school was shut down, you will also be asked questions about what has happened in your life more recently.** It is important that you know that all of your responses are anonymous. This means that no one will know that it is you who answered these questions. We will audiotape and transcribe your interview. Your name will be nowhere in the transcript of your interview. If you agree to participate in this interview, you will receive a \$10 gift card that you can use here at Fort Peck. If you would like a copy of your interview please let us know and we will make sure that you receive a copy of the transcript from our discussion.

What are the risks?

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What are the benefits?

The information gathered in this interview will help us understand how the COVID-19 pandemic has impacted young people at Fort Peck so that we can help the Tribes, schools and other resources at Fort Peck you and your family now and in the future. We would also like you to know that if you tell us about any abusive situation you are experiencing or have experienced, we will need to report that to the appropriate services here at Fort Peck so that you can receive assistance.

Who gets access to information from this interview?

The research team has access to the data collected for this project. The *We Are Here Now* community advisory board will also have access to the data collected for this intervention. All responses in this interview are anonymous. Neither the research team nor the community advisory board will know who you are and what your responses to the interview are.

How am I informed about the results of the project, and when will they be released and presented to someone else?

We will publish the results and make presentations on the results **from the interviews that we conduct to agencies at Fort Peck and the Fort Peck Tribal Executive Board.** Your identity will never appear in a publication or in print or be discussed at a presentation. In addition, you will have the opportunity to learn

about the intervention results by contacting members of the research team, attending community meetings where we share the results of the project, and through local (Fort Peck Reservation) media.

Who is involved in We Are Here Now?

If you have any questions regarding this interview, please contact:

Paula FireMoon, Fort Peck Community College

Email: PFiremoon@fpcc.edu; Phone: 406.768.6300

Bob McAnnally, Fort Peck Institutional Review Board Chair

Email: bmcassin@gmail.co; Phone: 406.768.6300.

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Email: elizabeth.rink@montana.edu; Phone: 406.994.3833

Mark Quinn, Montana State University Institutional Review Board Chair

Email: MQuinn@montana.edu; Phone: 406-994-4707

CONSENT STATEMENT

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If you are 18 years or younger and you agree to participate in this interview, please read, complete, and sign the statement below. By signing this consent form, you are giving your verbal and written consent to complete this interview.

Minor: I have read the above and understand the discomfort, inconvenience, and risks associated with this interview.

I, _____, **agree** to participate in this interview.
Name of Minor

Minor Participant Signature: _____ *Date:* _____

Parent/Legal Guardian agreement for minor:

If as a parent or legal guardian you **do want** your child to participate in this interview, please read, complete, and sign the statement below.

Parent/Legal Guardian for Minor: I have read the above and understand the discomfort, inconvenience, and risks associated with this interview.

I, _____, **do agree** to have my child participate in this interview.
Name of Parent/Legal Guardian

Parent/Legal Guardian Signature: _____ *Date:* _____

Interview Administrator Signature: _____ *Date* _____

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: October 1, 2018

ClinicalTrials.gov ID: NCT03694418

Study Identification

Unique Protocol ID: R01MD012761

Brief Title: We Are Here Now: a Multi-level, Multicomponent Sexual and Reproductive
Health Intervention for American Indian Youth (NE)

Official Title: We Are Here Now: a Multi-level, Multicomponent Sexual and Reproductive
Health Intervention for American Indian Youth

Secondary IDs:

Study Status

Record Verification: October 2018

Overall Status: Not yet recruiting

Study Start: March 1, 2019 [Anticipated]

Primary Completion: November 30, 2021 [Anticipated]

Study Completion: November 30, 2022 [Anticipated]

Sponsor/Collaborators

Sponsor: Montana State University

Responsible Party: Principal Investigator

Investigator: Elizabeth Rink [erink]

Official Title: Associate Professor

Affiliation: Montana State University

Collaborators:

Oversight

U.S. FDA-regulated Drug: No

U.S. FDA-regulated Device: No

U.S. FDA IND/IDE: No

Human Subjects Review: Board Status: Pending

Board Name: Montana State University IRB

Board Affiliation: Mark Quinn

Phone: 994-4707

Email: mquinn@montana.edu

Address:

960 Technology Blvd. Room 127

Data Monitoring: Yes

FDA Regulated Intervention: No

Study Description

Brief Summary: N/E is a community-based participatory research (CBPR) multi-level, multi-component sexual and reproductive health (SRH) intervention, constructed on Ecological Systems Theory. N/E is based on Fort Peck tribal members' desire to implement a holistic SRH intervention for AI youth. N/E includes: 1) A school-based SRH curriculum called Native Stand, designed to address individual-level factors that lead to sexual risk behaviors; 2) a family-level curriculum called Native Voices, tailored to increase communication between adult family members and youth about SRH topics; 3) a cultural mentoring component at the community level that pairs AI youth with adults and elders to discuss traditional AI beliefs and practices about SRH; and 4) a mobilizing strategy to activate a multi-sectoral network of youth-servicing organizations at the systems level in Fort Peck to coordinate SRH services for AI youth. The overarching aim of this proposal is to refine, tailor, and finalize the components of N/E and evaluate its efficacy. We will use a cluster-randomized stepped-wedge design (SWD), in which 5 schools that AI youth from Fort Peck attend are the clusters to be randomized into the intervention 1 at a time, with all schools eventually being randomized to the intervention. The 5 schools are located in separate communities, mitigating the potential for cross-contamination. N/E is a 5-year study involving 456 15- to 18-year-old AI youth.

Detailed Description: N/E is a community-based participatory research (CBPR) multi-level, multi-component sexual and reproductive health (SRH) intervention, constructed on Ecological Systems Theory. N/E is based on Fort Peck tribal members' desire to implement a holistic SRH intervention for AI youth. N/E includes: 1) A school-based SRH curriculum called Native Stand, designed to address individual-level factors that lead to sexual risk behaviors; 2) a family-level curriculum called Native Voices, tailored to increase communication between adult family members and youth about SRH topics; 3) a cultural mentoring component at the community level that pairs AI youth with adults and elders to discuss traditional AI beliefs and practices about SRH; and 4) a mobilizing strategy to activate a multi-sectoral network of youth-servicing organizations at the systems level in Fort Peck to coordinate SRH services for AI youth. The overarching aim of this proposal is to refine, tailor, and finalize the components of N/E and evaluate its efficacy. We will use a cluster-randomized stepped-wedge design (SWD), in which 5 schools that AI youth from Fort Peck attend are the clusters to be randomized into the intervention 1 at a time, with all schools eventually being randomized to the intervention. The 5 schools are located in separate communities, mitigating the potential for cross-contamination. N/E is a 5-year study involving 456 15- to 18-year-old AI youth.

Our specific aims are:

AIM 1: Refine, tailor, and finalize the components of N/E. Our community advisory board and the Fort Peck-based and MSU-based research team will design culturally appropriate adaptations for N/E's 4 levels during the first year of the study, based on the analysis of our recently completed qualitative and quantitative research (focus groups, interviews, and surveys), as well as discussions with elders and community stakeholders.

AIM 2: Test the efficacy of N/E for 15- to 18-year-old AI youth. Our hypotheses are:

H1: AI youth who participate in N/E will demonstrate increased condom use at 3, 9, and 12 months. (12 months will be used in the Primary Outcome analysis; 3 and 9 months will be used in the Secondary Outcomes analysis.) H2: AI youth who participate in N/E will demonstrate increased use of other birth control at 3, 9, and 12 months. They also will demonstrate a decrease in sexual risk behaviors as measured by reduced number of sex partners, delayed onset of sexual intercourse, and decreased substance use during sex, at 3, 9, and 12 months. (Secondary Outcomes) H3: N/E parents/legal guardians and youth will demonstrate significantly increased communication about topics related to SRH at 3, 9, and 12 months. AI youth who participate in the cultural mentoring program will demonstrate significantly increased understanding of cultural values related to traditional AI beliefs regarding SRH at 3, 9, and 12 months. And AI youth who participate in N/E will report significantly increased use of SRH services at 3, 9, and 12 months as a result of improved coordination among education, health care, and social service agencies on the Fort Peck Reservation. (Tertiary Outcomes) AIM 3: Evaluate the fidelity and acceptability of N/E. N/E's fidelity and acceptability will be evaluated using qualitative methods, including focus groups, activity logs, and staff field notes and meetings.

Conditions

Conditions: Reproductive Behavior
Sexual Behavior

Keywords:

Study Design

Study Type: Interventional

Primary Purpose: Prevention

Study Phase: N/A

Interventional Study Model: Sequential Assignment
Stepped Wedge Design

Number of Arms: 3

Masking: None (Open Label)

Allocation: Randomized

Enrollment: 1008 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
<p>Cluster 1</p> <p>Cluster 1 is 1 school on the Fort Peck Reservation that will be randomized into the intervention in 2019. Cluster 1 will receive all four levels of the intervention including: 1) A school-based SRH curriculum called Native Stand, designed to address individual-level factors that lead to sexual risk behaviors; 2) a family-level curriculum called Native Voices, tailored to increase communication between adult family members and youth about SRH topics; 3) a cultural mentoring component at the community level that</p>	<p>Behavioral: We are here now: a multi-level, multi-component sexual and reproductive health intervention for American Indian youth</p> <p>N/E will be implemented simultaneously over the 9-month school year. Components include: 1) Individual Level- Native Stand 2) Family Level - Native Voices; 3) Community Level - Cultural mentoring program; and 4) Systems Level. The fourth level of N/E mobilizes the existing Epi Team to enhance the coordination and implementation of SRH services at Fort Peck.</p>

Arms	Assigned Interventions
pairs AI youth with adults and elders to discuss traditional AI beliefs and practices about SRH; and 4) a mobilizing strategy to activate a multi-sectoral network of youth-servicing organizations at the systems level in Fort Peck to coordinate SRH services for AI youth.	
<p>Cluster 2</p> <p>Cluster 2 includes 2 schools on the Fort Peck Reservation that will be randomized in the intervention in 2019-2020. Cluster 2 will receive all four levels of the intervention including: 1) A school-based SRH curriculum called Native Stand, designed to address individual-level factors that lead to sexual risk behaviors; 2) a family-level curriculum called Native Voices, tailored to increase communication between adult family members and youth about SRH topics; 3) a cultural mentoring component at the community level that pairs AI youth with adults and elders to discuss traditional AI beliefs and practices about SRH; and 4) a mobilizing strategy to activate a multi-sectoral network of youth-servicing organizations at the systems level in Fort Peck to coordinate SRH services for AI youth.</p>	<p>Behavioral: We are here now: a multi-level, multi-component sexual and reproductive health intervention for American Indian youth</p> <p>N/E will be implemented simultaneously over the 9-month school year. Components include: 1) Individual Level- Native Stand 2) Family Level - Native Voices; 3) Community Level - Cultural mentoring program; and 4) Systems Level. The fourth level of N/E mobilizes the existing Epi Team to enhance the coordination and implementation of SRH services at Fort Peck.</p>
<p>Cluster 3</p> <p>Cluster 3 are the remaining 2 schools on the Fort Peck reservation that will be randomized into the intervention in 2020-2021. Cluster 3 will receive all four levels of the intervention including: 1) A school-based SRH curriculum called Native Stand, designed to address individual-level factors that lead to sexual risk behaviors; 2) a family-level curriculum called Native Voices, tailored to increase communication between adult family members and youth about SRH topics; 3) a cultural mentoring component at the community level that pairs AI youth with adults and elders to discuss traditional AI beliefs and practices about SRH; and 4) a mobilizing strategy to activate a multi-sectoral network of youth-servicing organizations at the systems level in Fort Peck to coordinate SRH services for AI youth.</p>	<p>Behavioral: We are here now: a multi-level, multi-component sexual and reproductive health intervention for American Indian youth</p> <p>N/E will be implemented simultaneously over the 9-month school year. Components include: 1) Individual Level- Native Stand 2) Family Level - Native Voices; 3) Community Level - Cultural mentoring program; and 4) Systems Level. The fourth level of N/E mobilizes the existing Epi Team to enhance the coordination and implementation of SRH services at Fort Peck.</p>

Outcome Measures

Primary Outcome Measure:

1. Change in condom use during sexual intercourse at 3 months, 9 months and 12 months
Change in condom use during sexual intercourse will be measured as proportion of condom use during sexual intercourse will be measured using 2 items (number of times condom used relative to number of times had sexual intercourse).

[Time Frame: 3 months, 9 months and 12 months]

Secondary Outcome Measure:

2. Change in delayed onset of sexual intercourse at 3 months, 9 months and 12 months
Changes in delayed onset of sexual intercourse will be measured intercourse with 2 items (ever had sexual intercourse and age at first sexual intercourse)

[Time Frame: 3 months, 9 months and 12 months]

3. Change in decreased number of sex partners at 3 months, 9 months and 12 months
Change in decreased number of sex partners will be measured by 2 items (lifetime of sex partners and the number of sex partners in the past month)
[Time Frame: 3 months, 9 months and 12 months]
4. Change in frequency of sexual intercourse at 3 months, 9 months and 12 months
Change in frequency of sexual intercourse will be measured with 1 time (frequency of sexual intercourse in the past month)
[Time Frame: 3 months, 9 months and 12 months]
5. Change in number of pregnancies at 3 months, 9 months and 12 months
Change in number of pregnancies will be measure with 1 item (number of pregnancies)
[Time Frame: 3 months, 9 months and 12 months]
6. Change in increased use of birth control during sexual intercourse at 3 months, 9 months and 12 months
Change in the increased use of birth control during sexual intercourse will be measured with 3 items (type of birth control used and number of times birth control was used during sexual intercourse)
[Time Frame: 3 months, 9 months and 12 months]
7. Change in decreased alcohol/drug use concurrently sexual intercourse at 3 months, 9 months and 12 months
Change in decreased alcohol/drugs used concurrently with sexual intercourse will be measured with 1 item (substance use with sexual intercourse)
[Time Frame: 3 months, 9 months and 12 months]

Other Pre-specified Outcome Measures:

8. Change in increased parent/child communication about sexual and reproductive health topics at 3 months, 9 months and 12 months
Change in increased parent/child communication about sexual and reproductive health topics will be measured using a 24 item Likert scale, higher score = higher communication
[Time Frame: 3 months, 9 months and 12 months]
9. Change in increased usage of sexual and reproductive health services at 3 months, 9 months and 12 months
Change in increased usage of sexual and reproductive health services will be measured with 9 items (frequency, type and follow up of sexual and reproductive health services used)
[Time Frame: 3 months, 9 months and 12 months]

Eligibility

Minimum Age: 15 Years

Maximum Age: 18 Years

Sex: All

Gender Based: No

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- 15 to 18 years old
- a registered member of a federally recognized tribe or an associate tribal member
- a resident of Fort Peck with a parent/child guardian. Exclusion criteria are minimal due to the CAB's value of inclusion in the intervention.
- For inclusion in the systems-level component of the intervention, only those staff members who sit on the Epi Team as representatives of their respective agencies are eligible.

Exclusion Criteria:

- not meeting the aforementioned inclusion criteria
- having a medically identified physical or cognitive impairment that would impede their understanding of and participation in the educational content and activities of Native Stand, Native Voices, and the cultural mentoring program.

Contacts/Locations

Central Contact Person: Elizabeth Rink, PhD

Telephone: 406-994-3833

Email: elizabeth.rink@montana.edu

Central Contact Backup: Genevieve Cox, PhD

Telephone: 406-994-4622

Email: genevieve.cox@motnana.edu

Study Officials:

Locations: United States, Montana

Montana State University

Bozeman, Montana, United States, 59715

Contact: Elizabeth Rink, PhD 406-994-3833 elizabeth.rink@montana.edu

Contact: Genevieve Cox, PhD 406-994-4622

genevieve.cox@montana.edu

Sub-Investigator: Paula Brien-Firemoon

Fort PeckCommunity College

Poplar, Montana, United States, 59255

Contact: Paula Brien-FireMoon, **MA** 406-768-7653 PFiremoon@fpcc.edu

IPDSharing

Plan to Share IPD: No

There is no plan to have an IPD sharing plan at this point in time.

References

Citations:

Links:

Available !PD/Information:

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

A COVER PAGE

Project Title: We are here now - a multi-level, multi-component sexual and reproductive health intervention for American Indian youth	
Grant Number: 5R01MD012761-02	Project/Grant Period: 04/01/2018 - 11/30/2022
Reporting Period: 04/01/2018 - 11/30/2018	Requested Budget Period: 12/01/2018 -11/30/2019
Report Term Frequency: Annual	Date Submitted: 10/03/2018
Program Director/Principal Investigator Information: ELIZABETH LYNNE RINK, PHO BA 0TH Phone number: 406-994-3833 Email: elizabeth.rink@montana.edu	Recipient Organization: MONTANA STATE UNIVERSITY - BOZEMAN MONTANA STATE UNIVERSITY-BOZEMAN 309 Montana Hall BOZEMAN, MT 597170000 DUNS: 625447982 EIN: 1816010045A1 RECIPIENT ID:
Change of Contact PD/PI: No	
Administrative Official: TRACI MIYAKAWA MONTANA STATE UNIV (BOZEMAN) BOZEMAN, MT 59717 BOZEMAN, MT 59717 Phone number: 406-994-2381 Email: tracim@montana.edu	Signing Official: TRACI MIYAKAWA MONTANA STATE UNIV (BOZEMAN) BOZEMAN, MT 59717 BOZEMAN, MT 59717 Phone number: 406-994-2381 Email: tracim@montana.edu
Human Subjects: Yes HS Exempt: No Exemption Number: Phase III Clinical Trial: No	Vertebrate Animals: No
hESC: No	Inventions/Patents: No

8. ACCOMPLISHMENTS

8.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

Our study, Nen OnkUmbi/EdaHiYedo ("We Are Here Now," or N/E), builds on an 11-year collaborative research relationship between the Assiniboine and Sioux Tribes of the Fort Peck Reservation and Montana State University (MSU) researchers to prevent STIs, HIV, HCV, and teen pregnancy among AI youth.

N/E is a community-based participatory research (CBPR) multi-level, multi-component sexual and reproductive health (SRH) intervention, constructed on Ecological Systems Theory. N/E is based on Fort Peck tribal members' desire to implement a holistic SRH intervention for AI youth. N/E includes: 1) A school-based SRH curriculum called Native Stand, designed to address individual-level factors that lead to sexual risk behaviors; 2) a family-level curriculum called Native Voices, tailored to increase communication between adult family members and youth about SRH topics; 3) a cultural mentoring component at the community level that pairs AI youth with adults and elders to discuss traditional AI beliefs and practices about SRH; and 4) a mobilizing strategy to activate a multi-sectoral network of youth-serving organizations at the systems level in Fort Peck to coordinate SRH services for AI youth. The overarching aim of this proposal is to refine, tailor, and finalize the components of N/E and evaluate its efficacy. We will use a cluster-randomized stepped-wedge design (SWD), in which 5 schools that AI youth from Fort Peck attend are the clusters to be randomized into the intervention 1 at a time, with all schools eventually being randomized to the intervention. The 5 schools are located in separate communities, mitigating the potential for cross-contamination. N/E is a 5-year study involving 456 15- to 18-year-old AI youth.

Our specific aims are:

AIM 1: Refine, tailor, and finalize the components of N/E. Our community advisory board and the Fort Peck-based and MSU-based research team will design culturally appropriate adaptations for N/E's 4 levels during the first year of the study, based on the analysis of our recently completed qualitative and quantitative research (focus groups, interviews, and surveys), as well as discussions with elders and community stakeholders.

AIM 2: Test the efficacy of N/E for 15- to 18-year-old AI youth. Our hypotheses are:

H1: AI youth who participate in N/E will demonstrate increased condom use at 3, 9, and 12 months. (12 months will be used in the Primary Outcome analysis; 3 and 9 months will be used in the Secondary Outcomes analysis.)

H2: AI youth who participate in N/E will demonstrate increased use of other birth control at 3, 9, and 12 months. They also will demonstrate a decrease in sexual risk behaviors as measured by reduced number of sex partners, delayed onset of sexual intercourse, and decreased substance use during sex, at 3, 9, and 12 months. (Secondary Outcomes)

H3: N/E parents/legal guardians and youth will demonstrate significantly increased communication about topics related to SRH at 3, 9, and 12 months. AI youth who participate in the cultural mentoring program will demonstrate significantly increased understanding of cultural values related to traditional AI beliefs regarding SRH at 3, 9, and 12 months. And AI youth who participate in N/E will report significantly increased use of SRH services at 3, 9, and 12 months as a result of improved coordination among education, health care, and social service agencies on the Fort Peck Reservation. (Tertiary Outcomes)

AIM 3: Evaluate the fidelity and acceptability of N/E. N/E's fidelity and acceptability will be evaluated using qualitative methods, including focus groups, activity logs, and staff field notes and meetings.

H4: N/E will result in a viable and sustainable multi-level, multi-component SRH intervention for AI youth.

Our short-term goal is to integrate N/E into the existing Fort Peck infrastructure to ensure local sustainability. Our long-term goal is to produce a toolkit, including curriculum manuals, an SRH cultural mentoring program, and specific systems-level actions suitable for replication in other tribal communities. The public health impact is the prevention of STIs, HIV, HCV, and teen pregnancies in AI youth resulting in reduced sexual and reproductive health disparities and improved health in AI families and communities.

8.1.a Have the major goals changed since the initial competing award or previous report?

No

8.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

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8.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

For this reporting period, is there one or more Revision/Supplement associated with this award for which reporting is required?

No

8.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

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8.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

Dissemination of the notice of award for NE was made through Fort Peck Tribal Council meetings, meetings with Fort Peck Community-

College faculty, staff and students, and was published on the Montana State University webpage as well as in the Bozeman Chronicle. In addition, Dr. Rink was selected to give a Provost Distinguished Lecture at the Museum of the Rockies (9/17/18) to the academic and public community. As part of her Distinguished Lecture Dr. Rink presented on the process of developing NE in which she presented to the Although this dissemination of NE is not about the results from the study, it does provide information to the Fort Peck tribal community and the larger Montana State University and Montanans about the study.

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

The following will be completed during the next reporting cycle (12/01/18 to 11/30/19):

- * Implement baseline data collection in the 5 schools at Fort Peck between 3/01/19 to 6/01/19.
- * Begin implementation of Aim 2 to test the efficacy of NIE for 15- to 18-year-old AI youth. Implementation of NE will begin in 9/2019 in one school at Fort Peck. The first school to receive NE in 9/2019 has yet to be determined because, as outlined in our proposal and in keeping with our study's Stepped Wedge Design, we must collect baseline data first and then randomize the schools into the intervention.
- Implement systems level component of NE.
- * Manage data software REDCap.
- * Convene DMSP committee and 2 hold meetings.
- * Hold 4 community advisory board meetings and meet with community advisory board members individually as needed.

The following accomplishments have been completed during reporting period (4/01/18 -11/30/18) related to the study's specific aims (goals):

AIM 1. Refine, tailor, and finalize the components of *NIE*. Our community advisory board and the Fort Peck-based and MSU-based research team will design culturally appropriate adaptations for *NIE*'s 4 levels during the first year of the study, based on the analysis of our recently completed qualitative and quantitative research (focus groups, interviews, and surveys), as well as discussions with elders and community stakeholders.

- 3 community advisory board meetings have been held to refine, tailor and finalize the components of *NIE*, including Native Stand, Native Voices, the Cultural Mentoring Program, and the System's Level adaptations.
- 4 meetings have been held specifically with Paula Firemoon, Ramey GrowingThunder and Elizabeth Rink to discuss the integration of the Cultural Mentoring Program with Native Stand and Native Voices.
- 2 meetings have been held with members of the Fort Peck Epi Team to discuss the adaptation of reproductive health services for 15-18 year old tribal youth.
- 2 discussions have been held with elders to talk about *NIE*.
- Subawards have been established with Fort Peck Community College, the Fort Peck Tribes Language and Culture Department, and Northern Arizona University.
- 3 meetings (2 conference calls and 1 in-person) with Dr. Julie Baldwin at Northern Arizona University who is Dr. Rink's senior research mentor on the study, to discuss tailoring of *NIE*.
- 3 meetings with Adriann Ricker, consultant to discuss adaptation of systems level component of *NIE* including working with the schools to revise their sexual and productive health education policies and meetings with the Fort Peck Epi team to tailor their services for 15 - 18 year old tribal youth.
- Hiring of personnel with Fort Peck Community College has begun.
- Hiring of personnel and mentors with the Fort Peck Tribes Language and Cultural Program has begun.
- Hired research program manager to replace Elizabeth Bird.
- Initiation of ClinicalTrials.gov forms for approval has begun.

AIM 2: Test the efficacy of *NIE* for 15- to 18-year-old AI youth.

- Data collection instruments have been finalized by the community advisory board, Fort Peck based research team and the Montana State University (MSU) based research team.
- Participation in 2 REDCap trainings to establish data management systems of *NIE*.
- Data management systems, REDCap, has been used to create the data management components of the study including the development of the data entry systems for the youth and parent surveys.
- Institutional Review Board applications have been submitted to the Fort Peck IRS and the MSU IRS for review and approval.
- Study has been registered with ClinicalTrials.gov (NCT # 03694418)
- Discussions with school administrators and teachers in each of the 5 schools involved in *NIE* have begun to prepare for the baseline data collection from March 1, 2019 to June 1, 2019.

AIM 3: Evaluate the fidelity and acceptability of *NIE*. *NIE*'s fidelity and acceptability will be evaluated using qualitative methods, including focus groups, activity logs, and staff field notes and meetings.

- Aim 3 has not been implemented during this reporting period because the intervention has not started yet. However, per AIM 1 and AIM 2, the tailoring of *NIE* has been complemented, data collection instruments have been complemented and the research protocols for *NIE* are being reviewed and approved by the Fort Peck IRS and the MSU IRS.
- 2 conference calls have been held with Rachel Hallum-Montes, the study's evaluation consultant, to discuss and plan for the evaluation of the fidelity and acceptability of *NIE*.

Training and Professional Development completed during this reporting period (4/01/18 - 11/30/18) including the following:

- Attendance at 2 REDCap trainings.
- 3 meetings with Julie Baldwin, Dr. Rink's senior research mentor.
- Participation in 1 seminar on reproduction and sexuality with underserved populations.
- Dr. Rink mentored 1 undergraduate student intern as part of a summer internship program from June 2018 to August 2018.
- Research Program Manager (new hire) attended one week NIH training on NIH grants management and NIH.gov systems, protocols, policies and procedures in San Francisco in October 2018.
- Attendance at 1 seminar through the Center for American Indian and Rural Health Equity on quantitative data analysis with small populations.

C. PRODUCTS

C.1 PUBLICATIONS

Are there publications or manuscripts accepted for publication in a journal or other publication (e.g., book, one-time publication, monograph) during the reporting period resulting directly from this award?

No

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

Nothing to report

C.3 TECHNOLOGIES OR TECHNIQUES**C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES**

Have inventions, patent applications and/or licenses resulted from the award during the reporting period? No

If yes, has this information been previously provided to the PHS or to the official responsible for patent matters at the grantee organization?

C.5 OTHER PRODUCTS AND RESOURCE SHARING

Nothing to report

Survey Instruments	Survey instruments for youth and parent data collection
Protocols	Institutional Review Board Protocols for the MSU and Fort Peck IRBs
Data or Databases	REDCap
Evaluation Instruments	Evaluation tracking materials for systems level component of intervention
Educational aids or curricula	Adaptation of Native Voices for Assiniboine & Sioux Tribes

D. PARTICIPANTS

D.1 WHAT INDIVIDUALS HAVE WORKED ON THE PROJECT?

Individual	DOB	Academic	Education	Role	Cal	Aca	Sum	Foreign Org	Country	SS
ELRINK	Y	Rink, Elizabeth Lynne	OTH,BA,P HD	PD/PI	0.0	3.5	0.0			NA
GENEVIEVE.CO	Y	Genevieve, Cox	PhD	Research Program Manager	3.0	0.0	0.0			NA
JBALDWIN	Y	Baldwin, Julie Ann	PhD	Co-Investigator	10.0	0.0	1.0			NA
RGROWINGTH	Y	GrowingThunder, Ramey	MA	Co- UNDER Investigator	11.0	0.0	0.0			NA
PBRIEN-FIREMOON	Y	Brien-Firemoon, Paula	JMA	Co-Investigator	13.0	0.0	0.0			NA

Glossary of acronyms:

S/K - Senior/Key
 DOB - Date of Birth
 Cal - Person Months (Calendar)
 Aca - Person Months (Academic)
 Sum - Person Months (Summer)

Foreign Org - Foreign Organization Affiliation
 SS - Supplement Support
 RE - Reentry Supplement
 DI - Diversity Supplement
 OT - Other
 NA - Not Applicable

D.2 PERSONNEL UPDATES

D.2.a Level of Effort

Will there be, in the next budget period, either (1) a reduction of 25% or more in the level of effort from what was approved by the agency for the PD/PI(s) or other senior/key personnel designated in the Notice of Award, or (2) a reduction in the level of effort below the minimum amount of effort required by the Notice of Award?

No

D.2.b New Senior/Key Personnel

Are there, or will there be, new senior/key personnel?

Yes

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D.2.c Changes In Other Support

Has there been a change in the active other support of senior/key personnel since the last reporting period?

No

D.2.d New Other Significant Contributors

Are there, or will there be, new other significant contributors?

No

D.2.e Multi-PI (MPI) Leadership Plan

Viii there **be a** change in the MPI Leadership Plan for the next budget period?

NA

BIOGRAPHICAL SKETCHNAME: **Cox, Genevieve Ramsey**eRA COMMONS USER NAME: **Genevieve.Cox**

POSITION TITLE: Research Program Manager

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
University of New Hampshire	Ph.D.	06/2012	Sociology
West Virginia University	M.A.	08/2005	Applied Social Research
Ohio University	B.A.	06/2002	English and Theater

A. Personal Statement

As a community, cultural, and environmental sociologist, I am committed to better understanding how the intersection of identities and issues such as race, class, and gender should be considered in tandem with geography and context when trying to determine the ways that knowledge, attitudes, perceptions, and values inform problems of public health or community development. I completed my Ph.D. as a Community, Health, and Environment fellow and I have a broad range of experience working with community-based research. I have been involved in all stages of research projects from program management to data collection to analysis to program evaluation of applied health care interventions to the writing of findings in both scholarly publications and research briefs. I have training in quantitative, qualitative, and mixed methodology research design and analysis. My master's thesis and article entitled "Poor Women with Sexually Transmitted Infections: Providers' Perspectives on Diagnoses," looked at the role that stigma plays as a barrier to health care for low-income women with sexually transmitted infections so my applied research interests are directly related to the intervention of this study.

As an Assistant Professor at a community college for three years after graduate school focused on teaching, I kept active in the research world by being a member of the Regional Institutional Review Board at the University of Southern Maine. I then helped steer a nonprofit organization as its Program Director. My wide-ranging training and experience has helped inculcate a dedication to working with vulnerable and underserved populations. I carry this dedication with me in the community-based participatory research projects I am a part of.

B. Positions and Honors

2005-2006 Program Manager, National Visitor Use Monitoring Study of the Pacific Northwest. USDA Forest Service and Pennsylvania State University, Portland, Oregon

2010-2013 Instructor and Lecturer, Department of Sociology, University of New Hampshire, Durham, NH

2008-2013 Research Assistant, Carsey School of Public Policy, University of New Hampshire, Durham, NH

2013-2016 Assistant Professor of Sociology, Department of Social Sciences, Southern Maine Community College, South Portland, ME

2013-2016 Institutional Review Board Member, University of Southern Maine, Portland, ME

2016-2017 Program Evaluator, Partnerships for Health, Augusta, ME

2017-2018 Program Director, Renewal in the Wilderness, Portland, ME

2018-current Research Program Manager, Center for American Indian and Rural Health Equity, Montana State University, Bozeman, MT

Honors:

2007-2011 Community, Health, and Environment Fellowship, Departments of Sociology and Psychology, University of New Hampshire

2005 Velma K. Miller Award, Outstanding Graduate Student in Women's Studies, West Virginia University

C. Contributions to Science

Mentoring Future Scientists:

As a former college professor focused on teaching, my main contributions to science have been in working to mentor future scientists. In my past classes (which have totaled upwards of 50 classes taught), we have had a focus on current social problems through the scientific lens of evidence-based research. This works to expand the student's knowledge base beyond the personal and anecdotal to understanding larger structural patterns and historical influence. I am extremely proud to have been a part of so many students' understanding of the importance of the scientific method and evidence-based research beyond their own personal experience, especially at the community college level.

Community Context:

Much of my past written work has to do with utilizing the community context to better understand behaviors, attitudes, and outcomes within communities. My doctoral dissertation was entitled, "Culture, Place, and Identity in a Mobile Community" and focused on ways values and place identity combine to create a community cultural identity that participants often adhere to. Related articles, briefs, and research presentations:

- Cox, Genevieve R., Corinna Jenkins Tucker, Erin Sharp, Karen Van Gundy, and Cesar Rebellon. 2014. "Practical Considerations: Community Context in a Declining Rural Economy and Emerging Adults' Educational and Occupational Aspirations." *Emerging Adulthood*. 2 (3): 173-183.
- Cox, Genevieve R. and Corinna Jenkins Tucker. 2011. "No place like home: Place and community identity among North Country youth." New England Issue Brief No. 24. January, 2011. The Carsey Institute, University of New Hampshire: Durham, NH.
- March 23, 2013. "Place Identity and Artistic Visual Integration: Burning Man Participants in Portland, OR." Presentation at the Annual Meeting of the Eastern Sociological Association. Boston, MA.
- February, 2012. Genevieve Cox. "Urban Mobile Artists: Why Place Still Matters for Burners in Portland, Oregon." Presentation at the Annual Meeting of the Eastern Sociological Association. New York, NY.
- November, 2011. Erin Sharp, Genevieve Cox, Cesar Rebellon, Corinna Jenkins Tucker, and Karen Van Gundy. "The Power of Rural Youth: Findings from the Coos Youth Study." Presentation at the New Hampshire Annual Celebration of National Rural Health Day. Meredith, NH.

Familial Relationships:

My research has also looked at ways that familial context interacts with outcomes for adolescents in terms of violence within the family and how larger economic forces affect relationships within the family.

- Tucker, Corinna Jenkins, Genevieve R. Cox, Erin Sharp, Karen Van Gundy, Cesar Rebellon, and Nena Stracuzzi. 2013. "Sibling Proactive and Reactive Aggression in Adolescence." *Journal of Family Violence*. 28(3):299-310.
- Tucker, Corinna Jenkins and Genevieve R. Cox. 2011. "Coos teens' view of their family economic stress tied to quality of relationships at home." New England Issue Brief No. 28. October, 2011. The Carsey Institute, University of New Hampshire: Durham, NH.

Socioeconomic Status and Sexually Transmitted Infection:

My master's thesis and subsequent manuscript focus on ways that stigma affects the experience of STI diagnosis between a provider and a patient.

Cox, Genevieve R. 2011. "Poor Women with Sexually Transmitted Infections: Providers' Perspectives on Diagnoses." *Online Journal of Rural Nursing and Health Care*. 11(2).

E. IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?

Not Applicable

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?

NOTHING TO REPORT

E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?

Not Applicable

E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

NOTHING TO REPORT

F. CHANGES**F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE**

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

The challenges and delays encountered during this reporting period (4/01/18 to 11/30/18) and related actions/plans to resolve them are listed below.

* Elizabeth Bird resigned from her position in the beginning of the reporting period and new search had to be conducted to replace her. The search took several months longer than anticipated and was completed in August 2018. Currently there is a new hire who is working as the Research Program Manager for the study. The new hire began work on September 4, 2018.

* Two prominent elders died at Fort Peck, one in June 2018 and the other in July 2018. Both deaths were unexpected and were felt by all Fort Peck Tribal members. As a result several weeks were taken up with grieving and ceremonies to honor the passing of the two elders. There is of course no way to plan for these types of sorrowful events in tribal communities. Because of the role that the Fort Peck Tribal College and the Fort Peck Tribes Language and Culture Program have in the community study personnel were attentive to honoring the 2 deaths which delayed study activities.

* In the original proposal (that was truncated in the NOA by 4 months) the end of Year 1 baseline data collection was to be completed. The base line data collection was planned with the 5 schools in the study during the proposal submission process. Thus we could not change the base line data collection plans for Spring 2019 as schools have complicated academic schedules. Base line data collection will take place during Year 2 in Spring 2019 as initially planned as part of Year 1.

* All human subjects requirements were to be completed during Year 1 in the original proposal. The truncation of Year 1 in the NOA by 4 months has delayed this process. At present all the research protocols have been approved by the study's community advisory board; and Fort Peck IRB and MSU IRB are reviewing the research protocols for approval. It is anticipated that all human subjects requirements will be finalized by December 1, 2018 at the latest.

* Because of the time taken to recruit and hire a new research program manager and the death of 2 elders at Fort Peck, sub awards to Fort Peck Community College, the Fort Peck Tribes Language and Culture Program and Northern Arizona University, were late in getting executed.

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS**F.3.a Human Subjects**

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. SPECIAL REPORTING REQUIREMENTS

<p>G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS</p> <p>File(s) uploaded: FPIRB_FWA_2018.pdf</p>
<p>G.2 RESPONSIBLE CONDUCT OF RESEARCH</p> <p>Not Applicable</p>
<p>G.3 MENTOR'S REPORT OR SPONSOR COMMENTS</p> <p>Not Applicable</p>
<p>G.4 HUMAN SUBJECTS</p> <p>G.4.a Does the project involve human subjects?</p> <p>Yes</p> <p>Is the research exempt from Federal regulations?</p> <p>No</p> <p>Does this project involve a clinical trial?</p> <p>Yes</p> <p>If yes, is this an NIH-defined Phase III Clinical Trial?</p> <p>No</p>
<p>G.4.b Inclusion Enrollment Data</p> <p>Report Attached: 'We are here now' - a multi-level, multi-component sexual and reproductive health intervention for American Indian youth</p>
<p>G.4.c ClinicalTrials.gov</p> <p>Does this project include one or more applicable clinical trials that must be registered in ClinicalTrials.gov under FDAAA?</p> <p>Yes</p> <p>If yes, provide the ClinicalTrials.gov identifier, NCT number (e.g., NCT00654321) for those trials: NCT03694418</p>
<p>G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT</p> <p>Are there personnel on this project who are newly involved in the design or conduct of human subjects research?</p> <p>No</p>
<p>G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)</p> <p>Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?</p> <p>No</p>
<p>G.7 VERTEBRATE ANIMALS</p>

Does this project Involve vertebrate animals?

No

G.8 PROJECT/PERFORMANCE SITES

Performance Site	Site ID	Organization	Address
Primary: MONTANA STATE UNIVERSITY - BOZEMAN	625447982	MT-001	P.O. Box 173540 318 Herrick Hall BOZEMAN MT 597173540
Fort Peck Community College	102366432	MT-001	PO Box 398 Poplar MT 592559398
Fort Peck Assiniboine & Sioux Tribes Language & Culture Dept	106578164	MT-001	PO Box 1027 Poplar MT 592551027

G.9 FOREIGN COMPONENT

No foreign component

G.10 ESTIMATED UNOBLIGATED BALANCE**G.10.a Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25% of the current year's total approved budget?**

Yes

Estimated unobligated balance: 666930**G.10.b Provide an explanation for unobligated balance:**

The estimate unobligated balance will be greater than 25% because: 1) Year 1 was truncated by 4 months; 2) there was a new hire that had to be recruited and hired; 3) the subawards were delayed in getting executed because of the time allocated to getting the new hire and the death of 2 elders at Fort Peck during the Summer of 2018.

G.10.c If authorized to carryover the balance, provide a general description of how it is anticipated that the funds will be spent

The carryover funds will be used to complete the following:

- * Hold monthly team meetings and quarterly CAB meetings. When necessary, we will meet with CAB members individually.
- * Continue monthly trips to Fort Peck.
- * Recruit, hire, and train staff in Native Stand and Native Voices; identify the cultural mentors; purchase all necessary materials and supplies.
- * Collect baseline data from March 1, 2019 to June 1, 2019 as originally planned in Year 1.
- * Upon completion of the baseline data collection randomize the 5 schools for participation in the intervention.
- * Analyze baseline data collection in collaboration with the CAB.
- * Implement evaluation of the systems level intervention with the Fort Peck Epi Team.
- * Start the implementation of the full intervention in 1 school beginning September 1, 2019.
- * Establish DSM Committee and hold 2 meetings.
- * Establish contracts with study consultants.

G.11 PROGRAM INCOME**Is program Income anticipated during the next budget period?**

No

G.12 F&A COSTS**Is there a change in performance sites that will affect F&A costs?**

No

FWA#: **FWA00019355**
Institution: **Fort Peck Community College**
Expires: **06/20/2023**

OMB No. 0990-0278
Approved for use through July 31, 2020

**Federalwide Assurance (FWA)
for the Protection of Human Subjects**

1. Institution Filing Assurance

Legal Name: **Fort Peck Community College**
City: **Poplar** State/Province: **MT** Country: **USA**

Institutional Components

List below all components over which the Institution has legal authority that operate under a different name. Also list with an asterisk(*) any alternate names under which the Institution operates.

NOTE: The Signatory Official signing this Assurance must be legally authorized to represent the Institution providing this Assurance and all components listed below.

Name of Component or Alternate Names Used	City	State (or Country if Outside U.S.)
Fort Peck Community College IRB 1/1	Poplar	MT A

3. Statement of Principles

This Institution assures that all of its activities related to human subjects research, regardless of the source of support, will be guided by the following statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution. (indicate below)

The Belmont Report
The Declaration of Helsinki

4. Applicability

(a) This Assurance applies whenever this Institution becomes engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule), unless the research is otherwise exempt from the requirements of the Common Rule or the department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance.

(b) Optional: This Institution elects to apply the following to all of its human subjects research regardless of the source of support, except for research that is covered by a separate assurance:

The Common Rule and subparts B, C, and D of the HHS regulations at 45 CFR part 46

5, Assurance of Compliance with the Terms of the Federalwide Assurance

(a) This Institution assures that whenever it engages in research to which this Assurance applies, it will comply with the Terms of the Federalwide Assurance (contained in a separate document on the Office for Human Research Protections (OHRP) website).

6, Designation of Institutional Review Boards (IRBs)

This Institution assures that it will rely upon only IRBs registered with OHRP for review of research to which this FWA applies. This institution (a) designates the following internal IRB(s) for review of research under this Assurance; or (b) does not have an internal IRB and designates the following external IRB for review of all research to which this FWA applies or, if multiple external IRBs are relied upon, the following external IRB that reviews the largest percentage of research to which this FWA applies.

NOTE: Institutions designating internal IRBs do not need to designate any of the external IRBs upon which it relies.

**HHSIRB
Registration
Number**

Name of IRB as Registered with HHS

**Is the IRB Internal or
External to the Institution?**

1, Human Protection Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person)

First Name: **Joy**

Middle Initial:

Last Name: **Toavs**

Degrees or Suffix: **BA**

Institutional Title:

Administrative Officer

Institution:

Fort Peck Community College

Telephone: **406 768-5555**

FAX: **406 768-3026**

E-Mail: **jtoavs@fpcc.edu**

Address: P.O. Box 398

605 Indian Avenue

City: **Poplar**

State/Province: **MT**

Country:

USA

Signatory Official (i.e., Official Legally Authorized to Represent the Institution)

I have read and agree to the Terms of the Federalwide Assurance.

*I recognize that providing research investigators, **/RB** members and staff, and other relevant personnel with appropriate initial and continuing education and training about human subject protections will help ensure that the requirements of this Assurance are satisfied.*

Acting officially **in** an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure protections for human subjects as specified above. The IRB(s) that this institution relies upon will comply with the Terms of the Federalwide Assurance when reviewing research covered by this Assurance and possess appropriate knowledge of the local context in which this Institution's research will be conducted.

All information provided with this Assurance is up-to-date and accurate. I am aware that false statements could be cause for invalidating this Assurance and may lead to other administrative or legal action.

Signature: Wayne Two Bulls MS Ed.

Date: 06/20/2018

First Name: Wayne Middle Initial: Last Name: Two Bulls

Degrees or Suffix: MS Ed. Institutional Title: Vice President of Academics

Institution: Fort Peck Community College

Telephone: 406 768-6300 FAX: 406 768-6301 E-Mail: WTwoBulls@fpcc.edu

Address: P.O. Box 398
605 Indian Avenue

City: Poplar State/Province: MT Country: USA

2, FWA AQProval

The Federal wide Assurance for the Protection of Human Subjects for Institutions Within the United States submitted to **HHS** by the above Institution is hereby approved.

Assurance Number: FWA00019355

Expiration Date: 06/20/2023

Signature of **HHS** Approving Official: Gail Holloway

Date: 06/20/2018

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0990-0278 . The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: U.S. Department of Health & Human Services, OS/OCIO/PRA, 200 Independence Ave., S.W., Suite 336-E, Washington D.C. 20201, Attention: PRA Reports Clearance

Inclusion Enrollment Report

Inclusion Data Record (IDR) #: 200138

Delayed Onset Study ?: No

Enrollment Location: Domestic

Using an Existing Dataset or Resource: No

Clinical Trial: Yes

NIH Defined Phase III Clinical Trial: No

Study Title: 'We are here now' - a multi-level, multi-component sexual and reproductive health intervention for American Indian youth

Planned Enrollment

Racial Categories	Ethnic Gateaories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	
American Indian/Alaska Native	500	500		0	0					1000
Asian	0	0		0	0					0
Native Hawaiian or Other Pacific Islander	0	0		0	0					0
Black or African American	0	0		0	0					0
White	4	4		0	0					8
More than One Race	0	0		0	0					0
Unknown or Not Reported										
Total	504	504		0	0					1008

Cumulative Enrollment

NOTE: No cumulative enrollment data exists. Although prompted to do so, the PD/PI did not enter information. No data can be displayed.

Nen OnkUmbi/EdaHiYedo ("We Are Here Now")
**Informed Consent to Participate in Human Subjects Research with Montana State University in
Partnership with Fort Peck Community College**

What is this project about?

We Are Here Now is an intervention project with Fort Peck Community College and Montana State University. The purpose of this intervention is to teach youth at Fort Peck important things they need to know about sex so that they can stay healthy and not get a sexually transmitted disease, HIV, or Hepatitis C, and so that they can make healthy decisions about having children, getting pregnant, or getting someone pregnant. *We Are Here Now* also teaches Assiniboiné and Sioux youth about their culture and traditional beliefs and practices about what it means to be a young Native person who will soon be an adult.

Why me?

You have been selected to participate in *We Are Here Now* because you are a young person at Fort Peck. You may choose to participate or not participate at any time.

What happens to me if I decide to participate?

If you decide to be in *We Are Here Now*, you will participate in a survey that will take 50 to 60 minutes. You will be asked to complete this survey three more times during the next year so that we can keep track of any changes you may have in your beliefs and behaviors as a result of participating in *We Are Here Now*. You will be asked several questions about different topics related to sex, having children, and sexually transmitted diseases in order to learn about what you think about having children and what you know about sexually transmitted diseases. You will also be asked questions about your sexual behavior and experiences with drugs and alcohol. You will also be asked questions about your feelings and emotions and your traditional culture. It is important that you know that all of your responses on this survey are anonymous. This means that no one will know that it is you who answered these questions. Your responses will be kept track of in the computer that you are taking the survey on. Your name will be nowhere in the computer or on the survey. If you agree to participate in this survey, you will receive a \$10 gift card that you can use here at Fort Peck. Also by agreeing to participate in *We Are Here Now*, your parent/legal guardian is agreeing to participate in an educational program called *Native Voices*, and you are agreeing to be part of a cultural mentoring program with the Fort Peck Tribes' Language and Culture Department.

What are the risks?

There may be minor risks to agreeing to participate in the survey. Some of the questions may make you feel uncomfortable, sad, or confused. You may choose to stop the survey at any time or decline to answer a particular question. The questions will be about your life experiences as they relate to sex, drug and alcohol use, having children, sexually transmitted diseases, your feelings and emotions, and your understanding of your traditional culture. None of the things that you say on the survey will be connected to your name.

What are the benefits?

The information gathered in this survey will help the intervention's research team and members of the Fort Peck community to understand what kind of impact your participation in *We Are Here Now* is having on your decisions to avoid getting a sexually transmitted disease and your decisions about having children when you feel you are ready. We would also like you to know that if you tell us about any abusive situation you are experiencing or have experienced, we will need to report that to the appropriate services here at Fort Peck so that you can receive assistance.

Who gets access to information from this interview?

The research team has access to the data collected for this project. The *We Are Here Now* community advisory board will also have access to the data collected for this intervention. All responses on this survey will be anonymous. Neither the research team nor the community advisory board will know who you are and what your responses to the survey are.

How am I informed about the results of the project, and when will they be released and presented to someone else?

We will publish the intervention results and make presentations on the results from *We Are Here Now*. Your identity will never appear in a publication or in print or be discussed at a presentation. In addition, you will have the opportunity to learn about the intervention results by contacting members of the research team, attending community meetings where we share the results of the project, and through local (Fort Peck Reservation) media.

Who is involved in *We Are Here Now*?

If you have any questions regarding this survey please contact:

Paula FireMoon, Fort Peck Community College

Email: PFiremoon@fpcc.edu; Phone: 406.768.6300

Elizabeth Rink, Montana State University

Email: elizabeth.rink@montana.edu; Phone: 406.994.3833

CONSENT STATEMENT

If the research participant is a minor:

If you are 18 years or younger and you agree to participate in this survey, please read, complete, and sign the statement below. By signing this consent form you are giving your verbal and written consent to complete this survey.

Minor: I have read the above and understand the discomfort, inconvenience, and risks associated with this survey.

I, _____, **agree** to participate in this survey.
Name of Minor

Minor Participant Signature: _____ *Date:* _____

Parent/Legal Guardian agreement for minor:

If as a parent or guardian you **do want** your child to participate in this survey, please read, complete, and sign the statement below.

Parent/Legal Guardian for Minor: I have read the above and understand the discomfort, inconvenience, and risks associated with this survey.

I, _____, **do agree** to have my child participate in this survey.
Name of Parent/Guardian

Parent/Guardian Signature: _____ *Date:* _____

Survey Administrator Signature: _____ *Date:* _____

Introduction

This survey will ask you questions about yourself. Many of the questions are about topics related to sex, alcohol and drugs, how you talk to your parents about sex, and your life experiences. Please remember that all of your answers to the questions are anonymous. This means that no one will know that it was you who answered these questions. No one will know your name and your answers to the questions. Only the answers to the questions will be recorded, not your name.

Thank you for taking the time to complete this survey.

SECTION 1: DEMOGRPAHICS

1.1 What is your gender? Male Female

1.2 How old are you? _____ (age in years)

1.3 What town do you live in?

Frazer
Oswego
Wolf Point
Poplar
Brockton
Fort Kipp
Other _____

41 What grade are you in?

gth
10th
11th
12th

SECTION 2: CULTURAL IDENTITY *(terliary outcome variable)*

The next set of questions are related to your culture and what it means for you to be an American Indian.

2.1 How much do you now live by or follow an American Indian way of life?

- a. Not at all
- b. A little
- c. Some
- d. A lot

2.2 How much do you now live by or follow a White or Anglo way of life?

- a. Not at all
- b. A little
- c. Some
- d. A lot

2.3 How important is it to you to follow religious or spiritual beliefs which are based on traditional Indian beliefs?

- a. Not at all important
- b. Not very important

- c. Somewhat important
- d. Very important

2.4 How important is it to you to follow religious or spiritual beliefs that are based on Christian beliefs such as Catholic, Baptist, Mormon, etc.?

- a. Not at all important
- b. Not very important
- c. Somewhat important
- d. Very important

2.7. How proud are you to be an American Indian?

- a. Not at all proud
- b. Not very proud
- c. Somewhat proud
- d. Very proud
- e. I do not consider myself to be an American Indian.

2.8 What kinds of activities have you participated in over the past year?

- | | |
|--|---|
| <input type="checkbox"/> Gathering traditional foods | <input type="checkbox"/> Singing and drumming |
| <input type="checkbox"/> Beading | <input type="checkbox"/> Traditional ceremonies |
| <input type="checkbox"/> Hand/stick games | <input type="checkbox"/> Sweats |
| <input type="checkbox"/> Hunting | <input type="checkbox"/> Kinship History |
| <input type="checkbox"/> Using sacred medicine | <input type="checkbox"/> Going to Pow Wows |
| <input type="checkbox"/> Dancing at Pow Wows | <input type="checkbox"/> Learning what it means to be a |
| <input type="checkbox"/> Traditional beliefs about sex | man (if male)/woman(if female) |
| <input type="checkbox"/> Learning about what it means to be an adult | |
| <input type="checkbox"/> Sundance/Medicine lodge | |
| <input type="checkbox"/> Other (please describe): | |

SECTION 3: COMMUNICATION ABOUT SEX WITH PARENTS/LEGAL GUARDIAN *(tertiary outcome variable)*

Now you are going to be asked questions about what kinds of topics related to sex you do or do not talk with your parents/legal guardian about.

3.1. Have you talked with your parent/legal guardian about each of the following topics in the past year?

	YES	NO	I DON'T KNOW
a. What qualities are important in choosing close friends			
b. What qualities to look for in a boyfriend/girlfriend/life partner			
c. How boys' bodies change physically as they grow up			
d. How girls' bodies change physically as they grow up			
e. How women get pregnant and have babies			
f. Symptoms of sexually transmitted infections (STIs)			
g. Reasons why people like to have sex			

h. How well birth control can prevent pregnancy			
i. How to choose a method of birth control			
j. How to say no if someone wants to have sex and you don't want to			
k. How well condoms can prevent sexually transmitted infections (STIs)			
l. Menstruation (having menstrual periods)			
m. The importance of not pressuring other people to have sex			
n. How you will make decisions about whether or not to have sex			
o. Consequences of getting pregnant/getting someone pregnant			
p. How to use a condom			
q. Reasons why you should not have sex			
r. Masturbation			
s. What it feels like to have sex			
t. Homosexuality/people being gay			
u. Wet dreams measured for boys only			
v. What to do if a partner doesn't want to use a condom			
w. How people can prevent getting sexually transmitted infections (STIs)			
x. How you will know if you are in love			

SECTION 4: ACCESS TO REPRODUCTIVE HEALTH SERVICES(tertiary outcome variable)

This next set of questions is about where you go to get services like getting a pregnancy test, sexually transmitted disease test, or birth control.

4.1 Have you ever been to Indian Health Service or Fort Peck Tribal Health for things like condoms, birth control, a pregnancy test or a sexually transmitted disease test?

- a. yes
- b. no

4.2 If you need to get condoms, birth control, a pregnancy test, or a sexually transmitted disease test, where would you go? (Mark all that apply)

- a. Indian Health Services
- b. Fort Peck Tribal Health
- c. Roosevelt County Health Department
- d. Somewhere off the reservation
- e. The Hospital
- f. A private doctor
- g. Local stores
- h. School nurse
- i. Teachers or counselors in your school
- j. Elder
- k. Other

4.3 If you had to put your response on a scale, how uncomfortable or comfortable would you say you feel when a health care provider talks with you about birth control and STDs? Would you say you are:

- a. Very uncomfortable
- b. Slightly uncomfortable
- c. Neither uncomfortable or comfortable

- d. Slightly comfortable
- e. Very comfortable

4.4 In general, how satisfied or dissatisfied would you say you are with the birth control and STD information and services you have received from health care providers in the past?

- a. Very dissatisfied
- b. Somewhat dissatisfied
- c. Neither satisfied nor dissatisfied
- d. Somewhat satisfied
- e. Very satisfied

4.5 How likely is it that you will seek birth control or STD services from a health care provider in the next year?

- a. Not at all likely
- b. A little likely
- c. Moderately likely
- d. Very likely
- e. Extremely likely

Section 5: Sexual Behavior (*primary, secondary, tertiary outcome variables*)

The next questions ask you about your sexual behavior.

5.1 Have you ever had sexual intercourse? Yes No

If you have never had sexual intercourse, skip to Section 6.

5.2 How old were you when you had sexual intercourse for the first time?

- a. I have never had sexual intercourse
- b. 11 years old or younger
- c. 12 years old
- d. 13 years old
- e. 14 years old
- f. 15 years old
- g. 16 years old
- h. 17 years old or older

5.3 During your life, with how many people have you had sexual intercourse?

- a. 1 person
- b. 2 people
- c. 3 people
- d. 4 people
- e. 5 people
- f. 6 or more people

5.4 During the past month, how many people have you had sex with? _____ [# of people]

5.5 During the past month, how many TIMES have you had sex? _____ times

5.6 Of the times you had sex over the past month, how many TIMES was a condom used?
_____ times

5.7 Of the times you had sex over the past month, how many TIMES did you use birth control other than a condom, like birth control pills or having a depo shot?

_____times

Over the past month, did you drink alcohol or take any kind of drug and have sex? Yes No

5.9 Did you drink alcohol or use drugs before you had sexual intercourse the **last** time?

- a. I have never had sexual intercourse
- b. Yes
- c. No

5.10 The last time you had sexual intercourse, what one method did you or the person you had sex with use to prevent pregnancy? (*Select only one response.*)

- a. No method was used to prevent pregnancy
- b. Birth control pills
- c. Condoms
- d. An IUD (such as Mirena or ParaGard) or implant (such as Implanon or Nexplanon)
- e. A shot (such as Depo-Provera), patch (such as OrthoEvra), or birth control ring (such as NuvaRing)
- f. Withdrawal or some other method
- g. Not sure

5.11 How many times have you been pregnant or gotten someone pregnant?

- a. 0 times
- b. 1 time
- c. 2 or more times
- d. Not sure

5.12 Have you ever been tested for HIV, the virus that causes AIDS?

- a. Yes
- b. No
- c. Not sure

5.13 Have you ever been tested for other sexually transmitted diseases (STDs), such as genital herpes, chlamydia, syphilis, or genital warts?

- a. Yes
- b. No
- c. Not sure

5.14 Have you ever been told by a doctor or nurse that you had the HIV infection or any other sexually transmitted disease (STD)?

- a. Yes
- b. No
- c. Not sure

If yes, did you receive follow-up care? Yes No Not sure

5.15 Have you ever been tested for HCV (Hepatitis C)?

- a. Yes
- b. No

c. Not sure

5.16 Have you ever been told by a doctor or nurse that you had Hepatitis C?

- a. Yes
- b. No
- c. Not sure

If yes, did you receive follow-up care? Yes No Not sure

Section 6: Substance Use Questions (secondary outcome variables)

These next questions are about alcohol and drug use.

6.1 How old were you when you tried any of the following for the first time?

Alcohol	I have never tried	8 years old or younger	9 or 10 years old	11 or 12 years old	13 or 14 years old	15 or 16 years old	17 years old or older
Marijuana (grass, pot, weed, or reefer)	I have never tried	8 years old or younger	9 or 10 years old	11 or 12 years old	13 or 14 years old	15 or 16 years old	17 years old or older
Meth (speed, crystal, crank, or ice)	I have never tried	8 years old or younger	9 or 10 years old	11 or 12 years old	13 or 14 years old	15 or 16 years old	17 years old or older
Cocaine (powder, crack, or freebase)	I have never tried	8 years old or younger	9 or 10 years old	11 or 12 years old	13 or 14 years old	15 or 16 years old	17 years old or older
Ecstasy (MOMA)	I have never tried	8 years old or younger	9 or 10 years old	11 or 12 years old	13 or 14 years old	15 or 16 years old	17 years old or older
Heroin (smack, junk, or diesel)	I have never tried	8 years old or younger	9 or 10 years old	11 or 12 years old	13 or 14 years old	15 or 16 years old	17 years old or older
Steroids (pills or shots without a doctor's prescription)	I have never tried	8 years old or younger	9 or 10 years old	11 or 12 years old	13 or 14 years old	15 or 16 years old	17 years old or older
Inhalants (sniff glue, breathe the contents of aerosol spray cans, or inhale any paints or sprays to get hiQh)	I have never tried	8 years old or younger	9 or 10 years old	11 or 12 years old	13 or 14 years old	15 or 16 years old	17 years old or older

6.2 During your life, how many times have you used any of the following:

Alcohol	0 times	1-2 times	3-9 times	10-19 times	20-39 times	40-99 times	100 or more times
Marijuana (grass, pot, weed, or reefer)	0 times	1-2 times	3-9 times	10-19 times	20-39 times	40-99 times	100 or more times
Meth (speed, crystal, crank, or ice)	0 times	1-2 times	3-9 times	10-19 times	20-39 times	40-99 times	100 or more times
Cocaine (powder, crack, or freebase)	0 times	1-2 times	3-9 times	10-19 times	20-39 times	40-99 times	100 or more times
Ecstasy (MOMA)	0 times	1-2 times	3-9 times	10-19 times	20-39 times	40-99 times	100 or more times
Heroin (smack, junk, or diesel)	0 times	1-2 times	3-9 times	10-19 times	20-39 times	40-99 times	100 or more times
Steroids (pills or shots without a doctor's prescription)	0 times	1-2 times	3-9 times	10-19 times	20-39 times	40-99 times	100 or more times
Inhalants (sniff glue, breathe the contents of aerosol spray cans, or inhale any paints or sprays to get high)	0 times	1-2 times	3-9 times	10-19 times	20-39 times	40-99 times	100 or more times

6.3 During the past 30 days, how many times did you use any of the following:

Alcohol	0 times	1 time	2 times	3 to 5 times	6 to 9 times	10 to 19 times	20 or more times
Marijuana (grass, pot, weed, or reefer)	0 times	1 time	2 times	3 to 5 times	6 to 9 times	10 to 19 times	20 or more times
Meth (speed, crystal, crank, or ice)	0 times	1 time	2 times	3 to 5 times	6 to 9 times	10 to 19 times	20 or more times
Cocaine (powder, crack, or freebase)	0 times	1 time	2 times	3 to 5 times	6 to 9 times	10 to 19 times	20 or more times
Ecstasy (MOMA)	0 times	1 time	2 times	3 to 5 times	6 to 9 times	10 to 19 times	20 or more times

Heroin (smack, junk, or diesel)	0 times	1 time	2 times	3 to 5 times	6 to 9 times	10 to 19 times	20 or more times
Steroids (pills or shots without a doctor's prescription)	0 times	1 time	2 times	3 to 5 times	6 to 9 times	10 to 19 times	20 or more times
Inhalants (sniff glue, breathe the contents of aerosol spray cans, or inhale any paints or sprays to get high)	0 times	1 time	2 times	3 to 5 times	6 to 9 times	10 to 19 times	20 or more times

6.4 During the past 30 days, on how many days did you have 5 or more drinks of alcohol in a row-that is, within a couple of hours?

- a. 0 days
- b. 1 day
- c. 2 days
- d. 3 to 5 days
- e. 6 to 9 days
- f. 10 to 19 days
- g. 20 or more days

6.5 During your life, how many times have you used a needle to inject any illegal drug into your body?

- a. 0 times
- b. 1 time
- c. 2 or more times

SECTION 7: BELIEFS ABOUT PREGNANCY *(Other Variables)*

These questions are about your beliefs about pregnancy.

7.1. How old do you think a woman should be when she has her first child?

- a. YEARS OLD
- b. I don't know.

7.2. How old do you think a man should be when he has his first child?

- a. YEARS OLD
- b. I don't know.

7.3. If you or your partner/boyfriend/girlfriend had a child in the next year, please tell us how having a child would affect you. (Even if you don't have a partner right now, tell us what you think you would do if this happened.)

- a. It would interfere with my relationship with my partner.
 - i. Disagree
 - ii. Neither agree nor disagree
 - iii. Agree

- b. It would take away my freedom.
 - i. Disagree
 - ii. Neither agree nor disagree
 - iii. Agree
- c. It would interfere with my plans.
 - i. Disagree
 - ii. Neither agree nor disagree
 - iii. Agree
- d. It would be a real problem.
 - i. Disagree
 - ii. Neither agree nor disagree
 - iii. Agree
- e. It would fit in with my plans.
 - i. Disagree
 - ii. Neither agree nor disagree
 - iii. Agree
- f. My family would be upset or disappointed.
 - i. Disagree
 - ii. Neither agree nor disagree
 - iii. Agree
- g. My family would kick me out.
 - i. Disagree
 - ii. Neither agree nor disagree
 - iii. Agree
- h. It would give my life direction.
 - i. Disagree
 - ii. Neither agree nor disagree
 - iii. Agree
- i. It would make it difficult to get or keep a job.
 - i. Disagree
 - ii. Neither agree nor disagree
 - iii. Agree
- j. I would consider it a great gift.
 - i. Disagree
 - ii. Neither agree nor disagree
 - iii. Agree
- k. It would encourage me to keep my job or look for a better job.
 - i. Disagree
 - ii. Neither agree nor disagree
 - iii. Agree
- l. My family would support me.
 - i. Disagree
 - ii. Neither agree nor disagree
 - iii. Agree
- m. It would make it difficult to stay in school.

- i. Disagree
- ii. Neither agree nor disagree
- iii. Agree

7.4. If you or your partner got pregnant within the next year or are currently expecting a child, how likely do you think it is that you would do any of the following things? (Even if you don't have a partner right now, tell us what you think you would do if this happened.)

I WOULD ...

- a. Raise the baby.
 - i. Not at all likely
 - ii. Not very likely
 - iii. Somewhat likely
 - iv. Very likely
- b. Get married or stay married.
 - i. Not at all likely
 - ii. Not very likely
 - iii. Somewhat likely
 - iv. Very likely
- c. Put the baby up for adoption.
 - i. Not at all likely
 - ii. Not very likely
 - iii. Somewhat likely
 - iv. Very likely
- d. Give the child to a relative to raise.
 - i. Not at all likely
 - ii. Not very likely
 - iii. Somewhat likely
 - iv. Very likely

SECTION 8: BELIEFS ABOUT BIRTH CONTROL METHODS, STIs, & HCV (Other Variables)

These next questions are about your beliefs about birth control and sexually transmitted diseases.

8.1 I believe that ...

- a. Used correctly, most birth control methods will lower the chances a woman will get pregnant.
 - i. Disagree
 - ii. Neither Disagree nor Agree
 - iii. Agree
- b. Talking about birth control methods will make your partner uncomfortable.
 - i. Disagree
 - ii. Neither Disagree nor Agree
 - iii. Agree
- c. Using some birth control methods can be dangerous to a woman's health.
 - i. Disagree
 - ii. Neither Disagree nor Agree
 - iii. Agree
- d. Talking about birth control methods with your partner will bring the two of you a lot closer.

- i. Disagree
 - ii. Neither Disagree nor Agree
 - iii. Agree
- e. It is hard for Indian women to accept using birth control methods because at times in the past the federal government forced it on them.
- i. Disagree
 - ii. Neither Disagree nor Agree
 - iii. Agree
- f. Some birth control methods are too difficult to use correctly.
- i. Disagree
 - ii. Neither Disagree nor Agree
 - iii. Agree
- g. Most of my friends and same-age relatives who have sexual intercourse use some type of birth control method.
- i. Disagree
 - ii. Neither Disagree nor Agree
 - iii. Agree
- h. My friends and same-age relatives encourage me to use some type of birth control method every time I have sexual intercourse.
- i. Disagree
 - ii. Neither Disagree nor Agree
 - iii. Agree

8.2. I believe that ...

- a. My parents and most of my older relatives have talked with me about abstinence (not having sexual intercourse) as a method of birth control.
- i. Disagree
 - ii. Neither Disagree nor Agree
 - iii. Agree
- b. My parents and most of my older relatives have talked with me about the importance of using some type of birth control method.
- i. Disagree
 - ii. Neither Disagree nor Agree
 - iii. Agree
- c. I will insist on using a condom with a new sexual partner, even if my partner doesn't want to.
- i. Disagree
 - ii. Neither Disagree nor Agree
 - iii. Agree
- d. If I were going to have sex in the next year, I would use condoms.
- i. Disagree
 - ii. Neither Disagree nor Agree
 - iii. Agree
- e. I would avoid using condoms if at all possible.
- i. Disagree
 - ii. Neither Disagree nor Agree
 - iii. Agree

- f. Using condoms makes sex feel unnatural.
 - i. Disagree
 - ii. Neither Disagree nor Agree
 - iii. Agree
- g. You feel closer to your partner when you don't use condoms.
 - i. Disagree
 - ii. Neither Disagree nor Agree
 - iii. Agree
- h. If I decided to have sexual intercourse with someone, I'm quite certain I could get my partner to agree to use condoms.
 - i. Disagree
 - ii. Neither Disagree nor Agree
 - iii. Agree
- i. If my partner wanted to use a condom, we could use one correctly.
 - i. Disagree
 - ii. Neither Disagree nor Agree
 - iii. Agree
- j. I would never talk to a sex partner about using condoms.
 - i. Disagree
 - ii. Neither Disagree nor Agree
 - iii. Agree

8.3 The next few questions are about Hepatitis C (HCV). Answer True or False.

- | | | |
|--|------|-------|
| a. HCV has no long-term effects on your health..... | True | False |
| b. It is possible to be vaccinated against HCV..... | True | False |
| c. People who have injected drugs are not at risk for HCV..... | True | False |
| d. HCV can be transmitted by tattooing and body piercing..... | True | False |
| e. All people who have HCV can be cured..... | True | False |
| f. HCV can be transmitted by sharing razors or toothbrushes..... | True | False |
| g. A person can get HCV by sharing a needle and syringe with someone when injecting drugs..... | True | False |
| h. A woman can get HCV through having sex with a man..... | True | False |
| i. A person can get HCV from mosquitos..... | True | False |
| j. Someone who looks very healthy can pass on HCV..... | True | False |

SECTION 9: CONTRACEPTIVE & CONDOM USE SELF-EFFICACY (Other variables)

We are now going to ask you some questions about what is important to you when selecting a birth control method to use when you have sex.

9.1 Indicate how important or unimportant these things about birth control are to you when selecting a birth control method to use to prevent pregnancy. Use this scale for your answers:

- 1. Not important
- 2. Slightly important
- 3. Moderately important
- 4. Very important
- 5. Extremely important

- a. Does not require me to touch my partners genitals

1	2	3	4	5
---	---	---	---	---

b. Is not messy to use.

1 2 3 4 5

c. Does not have to be washed or stored.

1 2 3 4 5

d. Can be bought without seeing a health care provider or getting a prescription

1 2 3 4 5

e. Can be used without your knowing about it.

1 2 3 4 5

f. Only needs to be used when I have sex.

1 2 3 4 5

g. Reduces your chances of getting HIV.

1 2 3 4 5

h. Reduces your chances of getting an STD other than HIV.

1 2 3 4 5

i. Does not cause side effects like bleeding, cramps, weight gain, or changes in mood in [NAME].

1 2 3 4 5

j. Does not cause pain or irritation.

1 2 3 4 5

k. Will not decrease sexual pleasure for you or [NAME].

1 2 3 4 5

l. Is effective in preventing pregnancy.

1 2 3 4 5

m. It is inexpensive.

1 2 3 4 5

n. It is easy to use.

1 2 3 4 5

o. It is a method you can control.

1 2 3 4 5

p. It is a method your partner likes.

1 2 3 4 5

9.2 Next we are going to ask some questions about how confident you are using a condom. Use this scale for your answers:

- 1 Not at all confident
- 2 Slightly confident
- 3 Moderately confident
- 4 Very confident
- 5 Extremely confident

- a. How confident are you that you could suggest using a condom even if you were afraid that your partner would reject you?
1 2 3 4 5
- b. How confident are you that you could suggest using a condom even if you were unsure of how your partner felt about condoms?
1 2 3 4 5
- c. How confident are you that you could suggest using a condom even if you were afraid that your partner would think that you have had sex with another person before?
1 2 3 4 5
- d. How confident are you that you could suggest using a condom even if you were afraid that your partner would think you have an STD?
1 2 3 4 5
- e. How confident do you feel in your ability to discuss using condoms with your partner?
1 2 3 4 5
- f. How confident do you feel in your ability to use a condom correctly?
1 2 3 4 5
- g. How confident do you feel in your ability to put a condom on without breaking the sexual mood with your partner?
1 2 3 4 5
- h. How confident do you feel in your ability to buy condoms without feeling embarrassed?
1 2 3 4 5
- i. How confident are you that you could remember to carry a condom with you in case you need one?
1 2 3 4 5
- j. How confident do you feel in your ability to use a condom with your partner even after drinking?
1 2 3 4 5
- k. How confident do you feel in your ability to use a condom with your partner even if you are high?
1 2 3 4 5
- l. How confident do you feel in your ability to use a condom with your partner even if you are sexually excited?
1 2 3 4 5

Good job! You are doing great so far! Please continue answering the questions.

9.3 The next questions ask about how sure you are that you could say NO to sex, alcohol, drugs, etc.-even if you have NEVER done any of these things before. *(Choose one answer for each question)*

- a. How sure are you that you would be able to say NO to having sex with someone you have known for a few days or less?
 - i. I Definitely Can Say No
 - ii. I Can Say No
 - iii. I Don't Know
 - iv. I Can't Say No
 - v. I Definitely Can't Say No
 - vi. Refuse to Answer

- b. How sure are you that you would be able to say NO to having sex with someone you want to date again?
- i. I Definitely Can Say No
 - ii. I Can Say No
 - iii. I Don't Know
 - iv. I Can't Say No
 - v. I Definitely Can't Say No
 - vi. Refuse to Answer
- c. How sure are you that you would be able to say NO to having sex with someone who you want to fall in love with you?
- i. I Definitely Can Say No
 - ii. I Can Say No
 - iii. I Don't Know
 - iv. I Can't Say No
 - v. I Definitely Can't Say No
 - vi. Refuse to Answer
- d. How sure are you that you would be able to say NO to having sex with someone who is pressuring you to have sex?
- i. I Definitely Can Say No
 - ii. I Can Say No
 - iii. I Don't Know
 - iv. I Can't Say No
 - v. I Definitely Can't Say No
 - vi. Refuse to Answer
- e. How sure are you that you would be able to say NO to having sex with someone after one or both of you have been drinking alcohol, smoking pot, and/or using drugs, etc.?
- i. I Definitely Can Say No
 - ii. I Can Say No
 - iii. I Don't Know
 - iv. I Can't Say No
 - v. I Definitely Can't Say No
 - vi. Refuse to Answer
- f. How sure are you that you would be able to say NO to having sex with someone who refuses to wear a condom?
- i. I Definitely Can Say No
 - ii. I Can Say No
 - iii. I Don't Know
 - iv. I Can't Say No
 - v. I Definitely Can't Say No
 - vi. Refuse to Answer
- g. How sure are you that you would be able to say NO to having sex with someone who you have had sex with before?
- i. I Definitely Can Say No
 - ii. I Can Say No
 - iii. I Don't Know
 - iv. I Can't Say No
 - v. I Definitely Can't Say No
 - vi. Refuse to Answer

SECTION 10: HEALTHY RELATIONSHIPS CHARACTERISTICS *(other variables)*

Think about a current close relationship (other than with a family member)-it could be a romantic relationship, a close friend, or another. (If you don't have a relationship like that right now, think about one you had in the past, or think about a relationship that you would like to have in the future.)

10.1 Are the following signs of a healthy relationship? *(Choose one answer for each question)*

- a. One partner acts jealous or possessive.
 - i. Yes
 - ii. No
 - iii. Don't Know
 - iv. Refuse to Answer
- b. One partner criticizes or puts the other one down.
 - i. Yes
 - ii. No
 - iii. Don't Know
 - iv. Refuse to Answer
- c. One of you threatens to hurt themselves or the other person if the relationship ever ends.
 - i. Yes
 - ii. No
 - iii. Don't Know
 - iv. Refuse to Answer
- d. You and your partner feel free to ask honestly for what you want.
 - i. Yes
 - ii. No
 - iii. Don't Know
 - iv. Refuse to Answer
- e. Your partner tries to change or control you (what you do and where you go).
 - i. Yes
 - ii. No
 - iii. Don't Know
 - iv. Refuse to Answer
- f. You and your partner are both comfortable with how physical the relationship is (or isn't).
 - i. Yes
 - ii. No
 - iii. Don't Know
 - iv. Refuse to Answer
- g. You bring out the best qualities in each other.
 - i. Yes
 - ii. No
 - iii. Don't Know
 - iv. Refuse to Answer
- h. You both feel close to each other (not just physically) and are willing to trust each other with personal stuff.

- i. Yes
- ii. No
- iii. Don't Know
- iv. Refuse to Answer

i. You make decisions jointly, with input from each partner.

- i. Yes
- ii. No
- iii. Don't Know
- iv. Refuse to Answer

j. Your partner thinks there are some situations in which it is OK for him or her to hit you.

- i. Yes
- ii. No
- iii. Don't Know
- iv. Refuse to Answer

SECTION 11: LIFE EVENTS (*other variables*)

11.1 Life Events are the next set of questions. For each life event, answer "No" if the event did *not* happen to you in the past year, or "Yes" if the life event *did* happen to you in the past year.

	No	Yes
1. Has a family member called you names, insulted you, or shamed you on a regular basis?	0	1
2. Was your partner very jealous of you a lot of the time?	0	1
3. Was your partner stingy toward you a lot of the time?	0	1
4. Have you lived with someone who spent a lot of money gambling?	0	1
5. Has a member of your partner's family called you names, insulted you, or shamed you on a regular basis?	0	1
6. Have you wanted to work but could not find a job or lost a job?	0	1
7. Has your partner wanted to work but could not find a job or lost a job?	0	1
8. Have you worried about getting kicked out of school, or what your parents would say about your school performance?	0	1
9. Have you worried about doing poorly in sports?	0	1
10. Were you or a close family member threatened or hurt by gang violence?	0	1
11. Have people gossiped or spread rumors about you?	0	1
12. Has someone important to you attempted suicide and survived?	0	1
13. Has someone important to you committed suicide?	0	1
14. Have you had a serious argument with a friend or friends?	0	1
15. Have you broken up with your partner?	0	1
16. Have you gotten in a car wreck in which someone was hurt or killed?	0	1
17. Has a relative taken over the care of your child (or children)?	0	1
18. Have you lost custody of your child (or children)?	0	1
19. Were you unable to find good child care for your child (or children)?	0	1
20. Has someone important to you died from causes other than suicide?	0	1
21. Have you or someone important to you had an alcohol or drug problem?	0	1
22. Have you or someone important to you gone to an alcohol or drug treatment program?	0	1
23. Have you or someone important to you "fallen off the wagon"?	0	1
24. Have you or someone important to you had a serious health problem, or injury or was hospitalized (not including alcohol or drug problems or relationship problems)?	0	1

SECTION 11: FEELINGS AND EMOTIONS (*other variables*)

You are almost done with the survey. These are the last questions.

11.1 Please mark which best describes how you felt during the past week.

- a. I felt that I could not shake off the blues even with help from my family or friends.
 - i. None of the time (0 days)
 - ii. Rarely or a little of the time (1-2 days)
 - iii. Some of the time (3-4 days)
 - iv. Most or all of the time (5-7 days)
- b. I felt depressed.
 - i. None of the time (0 days)
 - ii. Rarely or a little of the time (1-2 days)
 - iii. Some of the time (3-4 days)
 - iv. Most or all of the time (5-7 days)
- c. I thought my life had been a failure.
 - i. None of the time (0 days)
 - ii. Rarely or a little of the time (1-2 days)
 - iii. Some of the time (3-4 days)
 - iv. Most or all of the time (5-7 days)
- d. I felt fearful.
 - i. None of the time (0 days)
 - ii. Rarely or a little of the time (1-2 days)
 - iii. Some of the time (3-4 days)
 - iv. Most or all of the time (5-7 days)
- e. I felt lonely.
 - i. None of the time (0 days)
 - ii. Rarely or a little of the time (1-2 days)
 - iii. Some of the time (3-4 days)
 - iv. Most or all of the time (5-7 days)
- f. I had crying spells.
 - i. None of the time (0 days)
 - ii. Rarely or a little of the time (1-2 days)
 - iii. Some of the time (3-4 days)
 - iv. Most or all of the time (5-7 days)
- g. I felt sad.
 - i. None of the time (0 days)
 - ii. Rarely or a little of the time (1-2 days)
 - iii. Some of the time (3-4 days)
 - iv. Most or all of the time (5-7 days)
- h. I felt crabby.
 - i. None of the time (0 days)
 - ii. Rarely or a little of the time (1-2 days)
 - iii. Some of the time (3-4 days)
 - iv. Most or all of the time (5-7 days)
- i. I felt hopeless.
 - i. None of the time (0 days)
 - ii. Rarely or a little of the time (1-2 days)

- iii. Some of the time (3-4 days)
- iv. Most or all of the time (5-7 days)

j. I felt like no one cared.

- i. None of the time (0 days)
- ii. Rarely or a little of the time (1-2 days)
- iii. Some of the time (3-4 days)
- iv. Most or all of the time (5-7 days)

k. I felt discouraged.

- i. None of the time (0 days)
- ii. Rarely or a little of the time (1-2 days)
- iii. Some of the time (3-4 days)
- iv. Most or all of the time (5-7 days)

11.2. During the past week

a. Have you often worried that you have made a fool of yourself in front of other people?

- i. No
- ii. Yes

b. Have you often worried that you have made a mistake or done something the wrong way?

- i. No
- ii. Yes

c. Have you been almost always worried about something?

- i. No
- ii. Yes

d. Have you been very worried about whether other people like you?

- i. No
- ii. Yes

e. Have you often gotten worried or nervous?

- i. No
- ii. Yes

YOU ARE FINISHED WITH THE SURVEY! THANK YOU VERY MUCH FOR TAKING THE TIME TO COMPLETE THE SURVEY. PLEASE REMEMBER THAT NONE OF YOUR RESPONSES WILL BE ASSOCIATED WITH YOUR NAME. IF YOU HAVE ANY QUESTIONS ABOUT THIS SURVEY PLEASE ASK US.

***Nen OnkUmbi/EdaHiYedo* {"We Are Here Now"}**
Informed Consent to Participate in Human Subjects Research with Montana State University in Partnership with Fort Peck Community College

What is this project about?

We Are Here Now is an intervention project with Fort Peck Community College and Montana State University. ***Nen OnkUmbi/EdaHiYedo* {"We are Here Now," or NIE}** derives from the Assiniboine (*Nen OnkUmbi*) and Sioux (*EdaHiYedo*) names for their traditional coming-of-age ceremonies. The purpose of this program is to teach youth at Fort Peck important things they need to know about sex so that they can stay healthy and not get a sexually transmitted disease, HIV, or Hepatitis C, and so that they can make healthy decisions about having children, getting pregnant, or getting someone pregnant. *We Are Here Now* also includes tribal elders and leaders teaching Assiniboine and Sioux youth about their culture and traditional beliefs and practices about what it means to be a young Native person who will soon be an adult. In addition to working with youth, *We Are Here Now* also is offering education to parents/legal guardians about how to speak with their children about sensitive topics related to sex.

Why me?

You and your child have been invited to participate in *We Are Here Now* and to help gather information about the program and its effects. Your participation in this intervention is entirely voluntary. You can choose not to participate at any time. You and your child may withdraw from the intervention at any time without negative consequences. Your participation in *We Are Here Now* is your choice.

What happens to me if I decide to participate?

If you agree to participate in *We Are Here Now*, you will be with other guardians or parents of young people who are participating in *We Are Here Now*, and you will learn about how to talk with your child about sex. *We Are Here Now* is a project that educates youth and their guardians/parents about sexual and reproductive health. As a participant in *We Are Here Now*, you will be talking with other guardians/parents about healthy sexual behaviors and about how to talk with your children about sex. You will be asked to complete a survey specifically for guardians/parents about how you talk to your child about sex and what kinds of things about sex you speak with them about. You will receive an incentive of \$20 for this first survey, and then \$10 each time you attend the four *Native Voices* sessions (at 2 of these sessions you will again fill out the survey). Finally, you will receive a \$25 incentive for completing the final survey after the end of the program.

What are the risks?

Some of the questions may make you feel a bit uncomfortable. For example, we will ask you about what kinds of sexual topics you talk about with your child.

What are the benefits?

Through this program you will learn about ways to speak effectively with your child about sex and topics related to sexual health. The information gathered in this survey will help the intervention's research team and members of the Fort Peck community to understand what kind of impact your participation in *We Are Here Now* is having on your decisions to talk with your child about sensitive topics related to sex.

Who gets access to information from this interview?

All responses on this survey will be anonymous. Only one person, Paula FireMoon, will know that you participated, because she will keep this signed consent form in a locked file cabinet in her locked office. Neither she nor the rest of the research team, nor the community advisory board, will know what your individual responses to the survey are. The research team will have access to the anonymous data collected for this project. The *We Are Here Now* community advisory board will also have access to the anonymous data collected for this intervention.

How am I informed about the results of the project. and when will they be released and presented to someone else?

We will publish the intervention results and make presentations on the results from *We Are Here Now*. Your identity will never appear in a publication or in print or be discussed at a presentation. In addition, you will have the opportunity to learn about the intervention results by contacting members of the research team, by attending community meetings where we share the results of the project, and through local (Fort Peck Reservation) media.

Who is involved in *We Are Here Now*?

If you have any questions regarding this survey please contact:

Paula FireMoon, Fort Peck Community College

Email: PFiremoon@fpcc.edu; Phone: 406.768.6300

Elizabeth Rink, Montana State University

Email: elizabeth.rink@montana.edu; Phone: 406.994.3833

CONSENT STATEMENT

Parent/Legal Guardian for Minor: I have read the above and understand the discomfort, inconvenience, and risks associated with this survey.

I, _____, ***do agree*** to participate in this survey.
Name of Parent/Guardian

Parent/Guardian Signature: _____ *Date:* _____

SuNey Administrator Signature: _____ *Date* _____

"NenUnkUmbi/EdaHiYedo" (We Are Here Now)

PARENT SURVEY

We want to learn more about how you discuss sex with your child and what kinds of topics you discuss. We will be asking you a series of questions about how you talk to your child about sex and how you experience this communication. We thank you for your time.

SECTION 1: DEMOGRAPHICS

We would like to start by asking you some questions about yourself.

1. How old are you? _____
2. What is the highest grade you have completed? _____
3. What is your occupation? _____
4. What is your marital status? Please circle one.
a. married b. single c. living with a boyfriend/girlfriend

SECTION 2: COMMUNICATION WITH CHILD

Next we are going to ask some questions about how you feel about your ability to talk to your child about sex and what kinds of things about sex you specifically talk about.

1. How would you rate your ability to communicate with your child in general?
 - a. Difficult
 - b. Somewhat Difficult
 - c. Neither Difficult or Easy
 - d. Somewhat Easy
 - e. Easy
2. How would you rate your ability to communicate with your child about sex?
 - a. Difficult
 - b. Somewhat Difficult
 - c. Neither Difficult or Easy
 - d. Somewhat Easy
 - e. Easy
3. I would like to talk more often with my child about sex and sexuality.
 - a. Yes
 - b. No

4. Have you ever talked with your child about each of the following topics?

	YES	NO	I DON'T KNOW
a. What qualities are important in choosing close friends			
b. What qualities to look for in a boyfriend/girlfriend/life partner			

c. How to ask someone out on a date			
d. How boys' bodies change physically as they grow up			
e. How girls' bodies change physically as they grow up			
f. How women get pregnant and have babies			
g. Symptoms of sexually transmitted infections (STIs)			
h. Reasons why people like to have sex			
i. How well birth control can prevent pregnancy			
j. How to choose a method of birth control			
k. How to say no if someone wants to have sex and you don't want to			
l. How well condoms can prevent sexually transmitted infections (STIs)			
m. Menstruation (having menstrual periods)			
n. The importance of not pressuring other people to have sex			
o. How your child will make decisions about whether or not to have sex			
p. Consequences of getting pregnant/getting someone pregnant			
q. How to use a condom			
r. Reasons why your child should not have sex at this time			
s. Masturbation			
t. What it feels like to have sex			
u. Homosexuality/people being gay			
v. Wet dreams [measured for parents of boys only]			
w. What to do if a partner doesn't want to use a condom			
x. How people can prevent getting sexually transmitted infections (STIs)			
v. How your child will know if he/she is in love			

CLOSING STATEMENT

Thank you so much! That is all of our questions. As I said in the beginning, everything you told me today will remain private. Your name will not be on any information.

Nen OnkUmbi/EdaHiYedo (We Are Here Now)

Systems-Level Intervention Component BARRIERS & FACILITATORS DISCUSSION GUIDE

We Are Here Now is a 5-year intervention project with Fort Peck Community College and Montana State University. ***Nen OnkUmbi/EdaHiYedo*** ("**We are Here Now**," or ***NIE***) derives from the Assiniboine (*NenUnkUmbi*) and Sioux (*EdaHiYedo*) names for their traditional coming-of-age ceremonies. The overall goal of *We Are Here Now* is to reduce STIs, HIV, HCV, and teen pregnancy among American Indian (AI) youth living on the Fort Peck Reservation. There are four levels of *We Are Here Now*: a school-based curriculum called *Native Stand*; a parent curriculum called *Native Voices*; a cultural mentoring program with the Fort Peck Tribes' Language and Culture Department; and a systems-level component that involves increasing access to sexual and reproductive health (SRH) services for AI youth here at Fort Peck. As part of the systems-level component of *We Are Here Now*, we are working with the members of the Epi Team to identify and track the barriers and facilitators to provision of SRH services for AI youth here at Fort Peck. We would like to discuss with you what is and is not being provided to AI youth in your agencies and discuss possible solutions and steps to enhancing what and how SRH services are provided to AI youth. Our discussion today is based on the 8 service domains relative to improving SRH services of adolescents as outlined by the Centers for Disease Control and Prevention's (CDC) *Contraceptive and Reproductive Health Services for Teens: Evidence-based Clinical Best Practices*. We will use the results from our annual discussions to develop a monitoring plan tracking log to track our efforts to increase access to and utilization of SRH services for AI youth over the 5 years of *We Are Here Now*. As we have discussed, we will audio-tape the annual discussions, so please try to talk one person at a time. We would like everyone to be able to express their viewpoints without being interrupted. Do you have any questions for me before we begin the discussion? ***[Answer questions, if any]*** OK, let's get started.

SERVICE DOMAIN #1: CONTRACEPTIVE ACCESS

Discuss the extent to which your agency does or does not provide the services listed below. Please address what the barriers are to providing these services and/or what the factors are that facilitate the provision of these services.

- Offers same-day appointments
- Offers after-school-hours appointments
- Offers appointments during the weekend
- Takes/updates sexual health history at every visit
- Offers a wide-range of contraception (via prescription and/or dispensed onsite)
- Offers hormonal contraception or IUD at every visit to the clinical provider regardless of reason for visit (e.g., urgent, preventive, school health, sports physical, pregnancy testing, emergency contraception, sexually transmitted disease [STD] testing, HIV testing) to ensure that there are no missed opportunities

- Prescribes hormonal contraception without prerequisite exams or STI testing (i.e., without first requiring any of the following: Pap smear, pelvic examination, breast examination, or STD testing)

SERVICE DOMAIN #2: QUICK START PROVISION OF HORMONAL CONTRACEPTION/IUD

Discuss the extent to which your agency does or does not provide the services listed below. Please address what the barriers are to providing these services and/or what the factors are that facilitate the provision of these services.

- Initiates hormonal contraception using the Quick Start method¹
- Initiates hormonal contraception after the client has had a negative pregnancy test using Quick Start method
- Initiates hormonal contraception using the Quick Start method when an adolescent client is provided with emergency contraception where a pregnancy test is negative
- Offers Quick Start insertion of IUD

SERVICE DOMAIN #3: EMERGENCY CONTRACEPTION

Discuss the extent to which your agency does or does not provide the services listed below. Please address what the barriers are to providing these services and/or what the factors are that facilitate the provision of these services.

- Ensures emergency contraception is available to females
- Provides emergency contraception to females for future use
- Provides emergency contraception to males for future use

SERVICE DOMAIN #4: CERVICAL CANCER SCREENING

Discuss the extent to which your agency does or does not provide the service listed below. Please address what the barriers are to providing these services and/or what the factors are that facilitate the provision of these services.

- Adheres to current cervical cancer screening (Pap Smear) guidelines (i.e., initiate pap screening at age 21)

SERVICE DOMAIN #5: STI/HIV TESTING AND TREATMENT

Discuss the extent to which your agency does or does not provide the services listed below. Please address what the barriers are to providing these services and/or what the factors are that facilitate the provision of these services.

- Provides Chlamydia screening at least annually, or based on diagnostic criteria, consistent with USPSTF and CDC recommendations

- Offers Chlamydia screening for females using a urine or vaginal swab specimen
- Offers Chlamydia screening for males using a urine specimen
- Offers Gonorrhea screening for both females and males
- Offers HIV rapid testing for females and males as per CDC recommendations
- Offers expedited, patient-delivered partner therapy as an option for the treatment of uncomplicated chlamydia! infection

Additional question for HCV testing: Discuss the extent to which your agency does or does not provide HCV testing and treatment. In your discussion, address what the barriers are to providing HCV testing and treatment and/or what the factors are that facilitate the provision of HCV testing and treatment.

SERVICE DOMAIN #6: COST, CONFIDENTIALITY, CONSENT

Discuss the extent to which your agency does or does not provide the services listed below. Please address what the barriers are to providing these services and/or what the factors are that facilitate the provision of these services.

- Provides low-cost or no-cost contraceptive and reproductive health care services
- Provides confidential contraceptive and reproductive health care to adolescents without need for parental or caregiver consent (in accordance with state policy)

SERVICE DOMAIN #7: HEALTH CENTER/AGENCY INFRASTRUCTURE

Discuss the extent to which your agency does or does not provide the services listed below. Please address what the barriers are to providing these services and/or what the factors are that facilitate the provision of these services.

- Participates in the federal 340B drug discount purchasing program
- Uses electronic medical records (e.g., eClinical Works, Centricity, Epic, NextGen)
- Has systems in place to facilitate billing third party payers for contraceptive and reproductive health care services provided

SERVICE DOMAIN #8: HEALTH CENTER/AGENCY ENVIRONMENT

Discuss the extent to which your agency does or does not provide the services listed below. Please address what the barriers are to providing these services and/or what the factors are that facilitate the provision of these services.

- Has a counseling area that provides both visual and auditory privacy
- Has an examination room that provides visual and auditory privacy
- Has teen-focused magazines in the waiting room or examination areas
- Displays information on issues related to adolescent sexual and reproductive health

(e.g., confidentiality, cost, what services are available to adolescents)

- Has brief evidence-based or evidence-informed video or other interventions designed for adolescents

THANK YOU! That is it for our discussion today. Are there any questions? Or does anyone have anything more you would like to add?

NenUnkUmbi/EdaHiYedo (We are Here Now): COORDINATION & IMPLEMENTING MONITORING PLAN TRACKING LOG

AGENCY NAME: _____

AGENCY CONTACT NAME: _____

AGENCY CONTACT INFORMATION: _____

DATE TRACKING LOG FILLED OUT: _____

OVERVIEW AND INSTRUCTIONS

The purpose of this assessment is to help your health center identify current services, as well as opportunities for improving the quality of services for adolescent patients. Information collected through this assessment will be used to track health center progress in improving adolescent access to contraceptive and reproductive health services within Fort Peck.

This assessment should be completed every 3 months. Please meet with members of your multidisciplinary health care team to complete this assessment. This team-based approach to completing the assessment is important to ensure the information collected is accurate, and also to ensure that relevant team members are aware of the data being collected, and able to work together to identify opportunities for improving the quality of services offered to adolescents.

SERVICE DOMAIN #1: CONTRACEPTIVE ACCESS

Evidence Based Clinical Practice	Service Provided (check only one)			Barriers/Facilitators Description	Action Steps Required	Completion Timeline	Responsible Party
	Always	Sometimes	Never				
Offers same-day appointments							
Offers after-school hours appointments.							
Offers weekend appointments.							
Takes/updates sexual health history at every visit							
Offers a wide-range of contraception							
Offers hormonal contraception or IUD at every visit to the clinical provider regardless of reason for visit							
Prescribes hormonal contraception without prerequisite exams or STI testing							

SERVICE DOMAIN #2: QUICK START PROVISION of HORMONAL CONTRACEPTION/ IUD

Evidence Based Clinical Practice	Service Provided (check only on)			Barriers/Facilitators Description	Action Steps Required	Completion Timeline	Responsible Party
	Always	Sometimes	Never				
Initiates hormonal contraception using the Quick Start method							
Initiates hormonal contraception after the client has had negative pregnancy test using Quick Start method							
Initiates hormonal contraception using the Quick Start method when an adolescent client is provided with emergency contraception where a pregnancy test is negative							
Offers Quick Start Insertion of IUD							

SERVICE DOMAIN #3: EMERGENCY CONTRACEPTION

Evidence Based Clinical Practice	Service Provided (check only one)			Barriers/Facilitators Description	Action Steps Required	Completion Timeline	Responsible Party
	Always	Sometimes	Never				
Ensures emergency contraception is available							
Provides emergency contraception to females for future use							
Provides emergency contraception to males for future use							

SERVICE DOMAIN #4: CERVICAL CANCER SCREENING

Evidence Based Clinical Practice	Service Provided (check only one)			Barriers/Facilitators Description	Action Steps Required	Completion Timeline	Responsible Party
	Always	Sometimes	Never				
Adheres to current cervical cancer screening (Pap Smear) guidelines (i.e., initiate pap screening at age 21)							

SERVICE DOMAIN #5: STI/I-HIV/HCV TESTING AND TREATMENT

Evidence Based Clinical Practice	Service Provided (check only on)			Barriers/Facilitators Description	Action Steps Required	Completion Timeline	Responsible Party
	Always	Sometimes	Never				
Provides Chlamydia screening at least annually, or based on diagnostic criteria, consistent with USPSTF and CDC recommendations							
Offers Chlamydia screening for females using a urine or vaginal swab specimen							
Offers Chlamydia screening for males using a urine specimen							
Offers Gonorrhea screening for both females and males							
Offers HIV rapid testing for females and males as per CDC recommendations							
Offers expedited, patient-delivered partner therapy as an option for the treatment of uncomplicated chlamydia infection							
Offers HCV testing and treatment							

SERVICE DOMAIN #6: COST, CONFIDENTIALITY, CONSENT

Evidence Based Clinical Practice	Service Provided (check only one)			Barriers/Facilitators Description	Action Steps Required	Completion Timeline	Responsible Party
	Always	Sometimes	Never				
Provides low-cost or no-cost contraceptive and reproductive health care services							
Provides confidential contraceptive and reproductive health care to adolescents without need for parental or caregiver consent (in accordance with state policy)							

SERVICE DOMAIN #7: HEALTHCARE/AGENCY INFRASTRUCTURE

Evidence Based Clinical Practice	Service Provided (check only one)			Barriers/Facilitators Description	Action Steps Required	Completion Timeline	Responsible Party
	Always	Sometimes	Never				
Participates in the federal 340B drug discount purchasing program							
Uses electronic medical records							
Has systems in place to facilitate billing third party payers for contraceptive and reproductive health care services provided							

SERVICE DOMAIN #8: HEALTH CENTER/AGENCY ENVIRONMENT

Evidence Based Clinical Practice	Service Provided (check only one)			Barriers/Facilitators Description	Action Steps Required	Completion Timeline	Responsible Party
	Always	Sometimes	Never				
Has a counseling area that provides both visual and auditory privacy							
Has an examination room that provides visual and auditory privacy							
Has teen-focused magazines in the waiting room or examination areas							
Displays information on issues related to adolescent sexual and reproductive health (e.g., confidentiality, cost, what services are available to adolescents)							
Has brief evidence-based or evidence-informed video or other interventions designed for adolescents							

SERVICE DOMAN #SA: HEALTH CENTER STAFF TRAINING

Please indicate the number and percentage of **ALL health center staff** (e.g., all clinical and non-clinical staff that have direct contact with adolescent clients) that have received training in the following areas in the **past two years**.

In the past two years, staff received training on...	Number of staff	% of staff	Barriers/Facilitators Description	Action Steps Required	Completion Timeline	Responsible Party
Stages of adolescent development						
State-specific minors' rights to consent and confidentiality laws or provisions						
Cultural competency, including relevant Native beliefs and cultural traditions						
Continuous quality improvement (CQI)						
Youth-friendly services						
Strategies for serving non-English speaking populations (inc interpreter)						
Addressing the needs of lesbian, gay, bisexual, transgender, and queer (LGBTQ) youth						

Please indicate the number and percentage of **clinical staff** (e.g., MDs, advance practice clinicians, nurse-extenders) that have been trained in the following areas in the **past two years**.

In the past two years, clinical staff received training on...	Number of staff	% of staff	Barriers/Facilitators Description	Action Steps Required	Completion Timeline	Responsible Party
Contraceptive Services for Adolescents						
Use of the Quick Start method for initiation of hormonal contraception						
Use of Quick Start method for initiation of IUD						
IUDs for Adolescents						
Hormonal Implants						
Emergency Contraception						
Pap Smear Guidelines						
Breast exam guidelines						
Conducting a sexual health assessment/history for adolescents						
STI testing for adolescents						
HIV testing for adolescents						
Male sexual and reproductive health services						
Continuous quality improvement (CQI)						
Youth-friendly services						
Cultural competency, including relevant Native beliefs and cultural traditions						

SERVICE DOMAN #9: ADOLESCENT PATIENT DEMOGRAPHICS

NOTE: The following data may be collected via billing records, EMRs, and other methods. We are open to suggestions for other data collection methods based on your familiarity with your health center partners and your ability to collect data from your partners. It is recommended that you collect these data every 3 months.

Please note that by "visits" we mean any visit where an adolescent is seen by a health care team member - not only visits designated as reproductive/sexual health visits.

Please note that by "adolescent visits where contraceptive, reproductive, or sexual health services are provided" we mean any health center visit where contraceptive, reproductive, or sexual health services are provided to the adolescent patient, regardless of the primary reason for the visit.

For the past 3 months...	# adolescents seen (unduplicated)	# adolescent visits	# adolescent visits at which contraceptive, reproductive, or sexual health services are provided
FEMALE PATIENTS			
12-14 years			
15-18 years			
MALE PATIENTS			
12-14 years			
15-18 years			

For the past 3 months...	# adolescents tested for HIV	# positive results	# negative results
FEMALE PATIENTS			
12-14 years			
15-18 years			
MALE PATIENTS			
12-14 years			
15-18 years			

For the past 3 months...	# adolescents tested for chlamydia	# positive results	# negative results
FEMALE PATIENTS			
12-14 years			
15-18 years			
MALE PATIENTS			
12-14 years			
15-18 years			

For the past 3 months...	# adolescents tested for gonorrhea	# positive results	# negative results
FEMALE PATIENTS			
12-14 years			
15-18 years			
MALE PATIENTS			
12-14 years			
15-18 years			

Please complete the below table regarding the provision of hormonal contraception and IUD for adolescents in the J: last 3 months.

	# unduplicated adolescents provided...				
	The pill	Injectable contraception (e.g. Depo Provera)	IUD	Contraceptive implants (e.g. Nexplanon)	Emergency contraception (EC)
FEMALE PATIENTS					
12-14 years					
15-18 years					

NenUnkUmbi/EdaHiYedo (We are Here Now)

Community Advisory Board meeting form

Date of Meeting _____

Date form filled out (today's date): _____

Filled out once per quarter after each Community Advisory Board meeting.

Barriers or Facilitators to Intervention implementation discussed:	Type of contextual factors discussed (i.e. Social context, Environmental context, Political context, or Bureaucratic context):	Suggestions or solutions discussed:

NenUnkUmbi/EdaHiYedo (We are Here Now)

Whole Team meeting form

Date of Meeting _____

Date form filled out (today's date): _____

Filled out once every other month beginning February 2019.

Barriers or Facilitators to Intervention implementation discussed:	Type of contextual factors discussed (i.e. Social context, Environmental context, Political context, or Bureaucratic context):	Suggestions or solutions discussed:	Action and responsible party:	Adherence to Community-Based Participatory Research Principles?

NenUnkUmbi/EdaHiYedo (We are Here Now)

Fidelity Reach Log and Field Notes:

Date form filled out (today's date): _____

Filled out each day any component of the Intervention is delivered.

Intervention Delivery

Intervention Component Name (i.e. Native Stand, Native Voices, Cultural Mentoring, or Systems):	Date of Intervention delivery or meeting:	Length of time of Intervention delivery:	If Native Stand, Native Voices, or Cultural Mentoring, specific modules delivered:	Barriers to Intervention delivery:	Facilitators to Intervention delivery:

Field Notes:

Below to be filled out by the School Coordinator after any component of the Intervention is delivered.

Intervention Component Name (i.e. Native Stand, Native Voices, Cultural Mentoring, or Systems):	Environmental (weather, travel, etc.) barriers or facilitators to Intervention Delivery?	Social (basketball, mood of the group or general community etc.) barriers or facilitators to Intervention delivery?	Political or bureaucratic barriers or facilitators to Intervention delivery?	Suggestions or solutions?



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MEMORANDUM

TO: Elizabeth Rink

FROM: Mark Quinn *Mark Quinn*
Chair, Institutional Review Board for the Protection of Human Subjects

DATE: November 6, 2020

SUBJECT: "Nen Ünku?umbi/Edahiyedo ("We Are Here Now") - a Multi-level, Multi-component sexual and Reproductive Health Intervention for American Indian Youth - Pilot Study" [ER020518]

Thank you for submitting the follow-up report on the above research project. Reapproval of this project for an additional year will be reflected on the agenda of the next Institutional Review Board meeting. In the meantime, work on the project may continue. At the end of this approval period you will receive another follow-up form which will be used to evaluate this proposal for renewal. If the project extends beyond five years, you will need to submit a new application. Please keep track of the number of subjects who participate in the study and of any unexpected or adverse consequences of the research. If there are any adverse consequences, please report them to the committee within 3 calendar days. If there are serious adverse consequences, please suspend the research until the situation has been reviewed by the Institutional Review Board.

Any changes in the human subjects' aspects of the research should be approved by the committee before they are implemented.

It is the investigator's responsibility to inform subjects about the risks and benefits of the research. Although the subject's signing of the consent form, documents this process, you, as the investigator should be sure that the subject understands it. Please remember that subjects should receive a copy of the consent form and that you should keep a signed copy for your records.

In one year, you will be sent a questionnaire asking for information about the progress of the research. The information that you provide will be used to determine whether the committee will give continuing approval for another year. After initial approval, if the research is still in progress beyond a 5-year period, a completely new application will be required.



Fort Peck Tribal Institutional Review Board
For the Protection of Human Subjects
FWA00019355

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MEMORANDUM

TO: Elizabeth Rink, PhD, MSW

FROM: Robert McAnally, J.D. *Robert J. McAnally, J.D.*
Chairman, Institutional Review Board for the Protection of Human Subjects

DATE: November 1, 2023

RE: IRB Approval for the following: 1) Continued Data Analysis, 2) Continued Work with Community Advisory Board, 3) Design & Completion of "We Are Here Now" Tool Kit, 4) Implementation of Pilot Study that includes a Revised High School Survey, New Teacher Survey, and Revised Informed Consent Forms for Students and Parents, and New Informed Consent Forms for Teachers.

The Institutional Review Board has reviewed the above referenced requests and have officially granted approval on November 1, 2023.

As a reminder:

Please keep track of the number of subjects who participate in the study and of any unexpected or adverse consequences of the research. If there are any adverse consequences, please report them to the committee as soon as possible. If there are serious adverse consequences, please suspend research until the situation has been reviewed by the Institutional Review Board.

It is the investigator's responsibility to inform subjects about the risks and benefits of the research. Although the subjects' signing of the consent form, documents this process, you, as the investigator should be sure that the subject understands it. Please remember that subjects should receive a copy of the consent form and that you should keep a signed copy for your records.

Any future changes in the human subjects' aspects of the research will need approval by the Institutional Review Board before implementation.

The Fort Peck IRB requests that when you have a manuscript, thesis, or presentation prepared for public consumption, that you provide a copy to the Fort Peck IRB for prior approval. The IRB needs an opportunity to review the document pre-publication and may make recommendations to ensure the document appropriately respects the members of the Fort Peck Assiniboiné and Sioux Tribes.