

COVER LETTER

This document contains the informed consent for students, parents/legal guardians, and healthcare stakeholders participating in NE. IRB approvals are included.

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

Funding: The National Institute of Minority Health and Health Disparities National Institute of Health. Grant Number: R01 MD012701-02

ClinicalTrials.gov: NCT03694418

Update of this document was created on 9.25.24.

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
FAX: 406-994-4303
E-mail: cherylj@montana.edu

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 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 *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 from 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.

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:rrowingthunder@gm ail.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 from 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:* _____

APPROVED
MSU IRB
10/03/2018
Date approved

INSTITUTIONAL REVIEW BOARD

For the Protection of Human Subjects

FWA 00000165



MONTANA
STATE UNIVERSITY

2155 Analysis Drive
c/o Microbiology & Immunology
Montana State University
Bozeman, MT 59718
Telephone: 406-994-6783
FAX: 406-994-4303
E-mail: cherylj@montana.edu

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: 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 Assiniboine (*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 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.

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:* _____

NenUnkUmbi/EdaHiYedo ("We Are HereNow")

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.

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:* 10/03/2018 *Signature:* _____

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 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 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 topics related to sex.

APPROVED
MSU IRB
10/03/2018
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
10/03/2018
Date approved



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
FAX: 406-994-4303
E-mail: cherylj@montana.edu

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

MEMORANDUM

TO: FROM: Elizabeth Rink

Mark Quinn

DATE: Chair, Institutional Review Board for the Protection of Human Subjects August 9,

SUBJECT: 2019

"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 tribalelders 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

For the Protection of Human Subjects

FWA 00000165

960 Tedmology Blvd. Room 127
c/o Microbiology & Immunology
Montana State University
Bozeman, MT 59718
Telephone: 406-994-6783
FAX: 406-994-4303
E-mail: cherylj@montana.edu

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: April 20, 2020

SUBJECT: *"Nen Onk?umbi/Edahiyedo ("We Are Here Now'?) - a Multi-level, Multi-componentSexual and Reproductive Health Intervention for American Indian Youth- Pilot Study"*
[ERO20518]

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 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.

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

960 Technology Blvd. Room 127
c/o Microbiology & Immunology
Montana State University
Bozeman, MT 59718
Telephone: 406-994-6783
FAX: 406-994-4303
E-mail: cherylj@montana.edu

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') - 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 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 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 are here to 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

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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* _____

APPROVEDMSU IRB

Nen Unk Umbi/Eda Hi Yedo ("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 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 be asked 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 here to 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.

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.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*

Supplemental Funding Request In-Depth Interview Guide9-28-

20

PI: Elizabeth Lynne Rink, PhD MSW

APPROVED MSU 05/03/2021

IRB# E

09/30/2020
Date approved

Nen ÜnkUmbi/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 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?

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 over the past year during the COVID-19 pandemic.** 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 interview 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 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?

PI: Elizabeth Lynne Rink, PhD, MSW
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.

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 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.

Name of Parent/Legal Guardian

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

Interview Administrator Signature: _____ *Date* _____

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* _____

List of Community Resources for the Fort Peck Indian Reservation

Home School Coordinators:

Culbertson Public High School - 406-787-6241
Brockton Public High School - 406-786-3311
Poplar Public High School - 406-768-6830
Wolf Point Public High School - 406-653-1200
Frazer Public High School - 406-695-2241

Indian Health Service Mental Health/Public Health Departments:

Verne Gibbs Health Center, Poplar - 406-768-3491
Chief Redstone Health Clinic, Wolf Point - 406-653-1641

Fort Peck Tribes Health Agencies/Entities:

Spotted Bull Recovery Resource Center, Adolescent Counselors, Poplar - 406-768-3852
Family Violence Resource Center, Wolf Point - 406-653-1494
Health Promotion/Disease Prevention Wellness Program, Poplar - 406-768-3053

Other Local Governmental Agencies: (2 counties located on the Fort Peck Indian Reservation)

Roosevelt County Health Department, Wolf Point - 406-653-6223
Valley County Health Department, Glasgow - 406-228-6261

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 N/E)*** derives from the Assiniboine (*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 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 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 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



INSTITUTIONAL REVIEW BOARD
For the Protection of Human Subjects
FWA 00000165

2155 Analysis Drive
c/o Microbiology & Immunology
Montana State University
Bozeman, MT 59718
Telephone: 406-994-4706
FAX: 406-994-4303
E-mail: cherylj@montana.edu

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 *Mark Quinn C.J.*
Chair, Institutional Review Board for the Protection of Human Subjects
DATE: November 6, 2020
SUBJECT: "Nen Ünk?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

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

Fort Peck Community College
Box 398
Poplar, MT 59255
406-768-6300

Administrator: Paula FireMoon
(Acting) 406-768-6300
pfiremoon@fpcc.edu



MEMORANDUM

TO: Elizabeth Rink, PhD, MSW

FROM: Robert McAnally, J.D. *Robert J. McAnally, JD*
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 Assiniboine and Sioux Tribes.