

Nen ŪnkUmbi/EdaHiYedo Plus: a Multi-level Intervention to Reduce Health Disparities Among
American Indian Youth

Clinicaltrials.gov Study Documents: Consent forms & IRB approval

Protocol ID: R01MD012761-07

NCT ID: Not yet assigned

Date of approval by Fort Peck IRB: July 31st 2025



Fort Peck Tribal Institutional Review Board

For the Protection of Human Subjects
FWA00019355

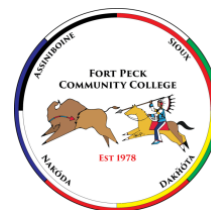
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Chair:

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

Administrator:
(Acting)

Paula FireMoon
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MEMORANDUM

TO: Dr. Elizabeth Rink, Molly Secor, PhD, RN, FSAHM, Julie Baldwin, PhD

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

DATE: IRB Approval July 31, 2025

RE: IRB Approval NE+ Project

The Institutional Review Board (IRB) has reviewed research protocols including the informed consents, data collection instruments and procedures, the intervention content and delivery method, and the inclusions of cultural teachings for NE+. The Fort Peck IRB determined all aforementioned research protocols to be intervention content and delivery, cultural teachings are age appropriate and appropriately contextualize to the Tribal communities on the Fort Peck Reservation where NE+ will be implemented.

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.

NenUnkUmbi/EdaHiYedo - Plus (“We Are Here Now- Plus”)
Informed Consent to Participate in Human Subjects Research with Montana State University, Northern Arizona University, and Mathematica in Partnership with Fort Peck Community College

What is this project about?

We Are Here Now-Plus (NE+) is an expanded intervention project with Fort Peck Community College and Montana State University. The purpose of NE+ 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. NE+ 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 NE+ 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 NE+, you will participate in a survey that will take 45 to 50 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 NE+. 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 NE+, your primary caregiver is agreeing to participate in the project's caregiver educational program.

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 project's team and members of the Fort Peck community to understand what kind of impact your participation in NE+ 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, Paula FireMoon and Olivia Johnson, 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. Paula Firemoon will be the only person who has access to your personal information. 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, Olivia nor the rest of the project 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 project 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 results from NE+ and make presentations on the results from the project. 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 results for NE+ by contacting Paula or, 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

Olivia Johnson, Fort Peck Community College

Email: ojohnson@fpcc.edu Phone: 406.768.6300

Bob McAnnally, Chair – Fort Peck Institutional Review Board

Email: bmcassin@gmail.com; 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:* _____

Caregiver 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.

Caregiver 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 Caregiver

Caregiver Signature: _____ *Date:* _____

Survey Administrator Signature: _____ Date _____

List of Community Resources for the Fort Peck 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
Redbird Woman Family 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

National Suicide Prevention Lifeline - 1-800-273-8255

**NenĪnkUmbi/EdaHiYedo-Plus (“We Are Here Now-Plus”)
Informed Consent to Participate in Human Subjects Research with Montana State
University, Northern Arizona University, Mathematica in Partnership with Fort Peck
Community College**

What is this project about?

We Are Here Now – Plus (NE+) is a project with Fort Peck Community College that expands our prior project, which took place from 2019 to 2023, in the schools with youth and their families at Fort Peck.. NE+ derives from the Assiniboiné (*NenĪnkUmbi*) and Sioux (*EdaHiYedo*) names for their traditional coming-of-age ceremonies. The purpose of our project 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 also teach students about how to prevent substance use, promote mental health, as well as how to have healthy relationships with others. NE+ 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, NE+ also is offering education to caregivers about how to speak with their children about topics related to substance use, mental health, and sexual risk behaviors.

Why me?

You and your child have been invited to participate in NE+ to help gather information about the project and its effects. Your participation in this project is entirely voluntary. You can choose not to participate at any time. You and your child may withdraw from the project at any time without negative consequences. Your participation in NE+ is your choice.

What happens to me if I decide to participate?

If you agree to participate in NE+, you will receive three individual education sessions with our Family – Community Coordinator. You will learn about how to talk with your child about prevention of substance use and sexual risk behaviors as well as how to promote positive mental health with your child. NE+ educates youth and their caregivers about substance use, mental health, and sexual and reproductive health. As a participant in NE+, you will be asked to complete a survey specifically for caregivers about how you talk to your child about substance use, mental health, and sexual and reproductive health. There is no cost to you if you agree to participate in this study. You will receive an incentive of \$20 for each of the three individual educational sessions you participate in.

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 topics related to substance use, mental health, and sexual and reproductive health you talk about with your child. A list of community resources is provided with this informed consent if you would like to speak with someone further about feelings that may have been brought up as a result of your participation in this project.

What are the benefits?

Through this project 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 project’s team and members of the Fort Peck community to understand what kind of impact your participation in NE+ is having on your decisions to talk with your child about substance use, mental health, and sexual and reproductive health.

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

Olivia Johnson, Fort Peck Community College

Email: ojohnson@fpcc.edu Phone: 406.768.6300

Bob McAnnally, Chair – Fort Peck Institutional Review Board

Email: bmcassin@gmail.com; Phone: 406.768.6300

Elizabeth Rink, Montana State University

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

CONSENT STATEMENT

Caregiver 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 Caregiver

Caregiver Signature: _____ *Date:* _____

Survey Administrator Signature: _____ *Date* _____

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Why me?

Research, including research from our first project in 2019 -2023, demonstrates that support relationships between students and school personnel is instrumental in promoting positive health behaviors among youth and helping them to be successful in school. School personnel you have been invited to participate in NE+ to help gather information about the project and its effects. Your participation in this project is entirely voluntary. You can choose not to participate at any time. You may withdraw from the project at any time without negative consequences. Your participation in NE+ is your choice.

What happens to me if I decide to participate?

If you agree to participate in NE+, you will participate in three education sessions with our School Coordinator, Olivia Johnson. You will learn about how to talk with students in a cultural respectful and safe way about prevention of substance use and sexual risk behaviors as well as how to promote positive mental health with your child. You will also learn how to make appropriate referrals for students about these health topics. As a participant in NE+, you will be asked to complete a survey specifically for school personnel about your experiences when students ask you about topics related to substance use, mental health, and sexual and reproductive health. There is no cost to you if you agree to participate in this study. You will receive an incentive of \$20 for each of the three education sessions you participate in with other school personnel.

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 topics related to substance use, mental health, and sexual and reproductive health students have asked you about. A list of community resources is provided with this informed consent if you would like to speak with someone further about feelings that may have been brought up as a result of your participation in this project.

What are the benefits?

Through this project you will learn about ways to speak with students in a cultural respectful way and how to appropriately refer them for assistance if they ask you questions about topics related to substance use, mental health, or sexual and reproductive health. The information gathered in this survey will help the project's team and members of the Fort Peck community to understand what kind of impact your role as a school personnel is having on students decisions and health.

Who gets access to information from this interview?

All responses on this survey will be confidential. Paula FireMoon and Olivia Johnson, 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, Olivia nor the rest of the project 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 project 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.

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Bob McAnnally, Chair – Fort Peck Institutional Review Board

Email: bmcassin@gmail.com; Phone: 406.768.6300

Elizabeth Rink, Montana State University

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

CONSENT STATEMENT

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

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

School Personnel Signature: _____ *Date:* _____

Survey Administrator Signature: _____ Date _____

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