INFORMED CONSENT FOR RESEARCH

We try to make this form easy to understand. But it may have words or ideas that are not clear to you. Please ask a member of the study team to explain anything you do not understand.

Study Title: Healing Lodge First Face Training Evaluation Study

Your name (Participant): **Your Healing Lodge email address (Participant):** **Your personal email address (Participant):**	**Today's Date:**

Name of Principal Investigators: Martina Whelshula, Ph.D.

Name of Co-Investigator(s): Heather Gray, PhD

Consent form version date or number: v1.0

Name and telephone number of study contact to contact with questions: Dr. Melinda Bowman melindab@healinglodge.org (509) 795-8342

Approving IRB: Portland Area IRB

Study Sponsor(s): National Institutes of Health

Key Information

- You are invited to take part in a study called “Healing Lodge First Face Training Evaluation Study.”
- Taking part in this study is voluntary. You have the choice to take part or not.
- If you choose to take part in the study, you will complete two 20-minute surveys, one before and one after your First Face training. You will be invited to complete another 20-minute survey in 3 months. These surveys will help us evaluate the First Face training.
- You will receive no compensation for your participation.
- You might have moments during the surveys when you feel stressed or anxious.
- Despite strong efforts to maintain your confidentiality, what you say in the surveys might be accidentally disclosed. However, we make strong efforts to protect your confidentiality, and you do not have to answer any questions you don’t want to.
- You might not benefit directly from this study, but we hope it will help us improve First Face.
- An alternative is to not participate in this study.

Introduction

You are invited to take part in a research study done by Dr. Martina Whelshula, PhD, Heather Gray, PhD, and people who work with these researchers.

Taking part in this study is voluntary. You have the choice to take part or not. If you take part in the study, you may leave the study at any time for any reason. If you decide to take part in this study, you will be asked to sign this form.

Purpose for the Study

The purpose of this study is to evaluate a culturally grounded training program, *xaʔtus* (meaning First Face) for Mental Health. This program will train you and other community members how to recognize and respond to youth and adults experiencing mental health crises and ways to serve as a bridge between these individuals and the help they need. All Healing Lodge staff are being asked to complete First Face training.

To evaluate First Face, we are asking all trainees to complete surveys before and after training, and again 3 months later. These surveys will measure knowledge about mental health and addiction, as well as the ability and confidence to respond appropriately to mental health crises. The study will help us understand whether the First Face training program influences mental health and attitudes, as well as responses to mental health crisis situations.

Reasons why you have been invited to be in this study

The reason why you have been invited to be part of this study is because you work at the Healing Lodge and are completing First Face training.

Period of Participation (how long you will be in this study)

If you choose to participate in this research study, you will be in this study for up to 3 months.

Procedures (what will happen during this study)

If you decide to take part in this study, you will complete surveys before and after your training and again in 3 months. Each survey will take 20 minutes to complete.

Collection of identifiable private information or identifiable biospecimens

The only identifiable information we will gather from you will be your name and your email addresses. We are asking for your name and email address only so that we can match up the surveys you complete today with the survey you will complete 3 months from now. After we collect all the data, we will create a computer database. In that database, your responses will be coded with a numeric ID instead of your name or email address. Only the study team will have access to your name or email address.

The computer database will be stored and accessed on a password-protected digital drive that is only accessible to the researchers. Paper copies of surveys and informed consent forms will be stored in locked file cabinets at the Healing Lodge. You will complete the 3-month post-training survey via an online survey platform

The information that you provide in these surveys will be used by the researchers on this project to write reports and manuscripts for dissemination in presentations, scholarly journals, and meetings with Tribal members. The information will also be used to recommend improvements to the First Face training. No identifying information about you will be included in any of these reports or recommendations.

Possible Risks, Discomforts, Side Effects, and Inconveniences

We anticipate that there will be limited risk to participants associated with this voluntary research study. The following are possible risks and side-effects associated with your participation in this study:

- Some of the questions in the surveys are of a personal nature. They may cause you to be embarrassed or stressed. You may ask to see the questions before deciding whether or not to participate in this study.
- Despite strong efforts to maintain your confidentiality, what you say in the surveys might be accidentally disclosed. However, we make strong efforts to protect your confidentiality, and you don't have to answer any survey questions you do not want to.

We will be happy to answer any questions you have about these risks. The contact details for the study team are available to you at the bottom of this form if you have any questions or concerns.

Alternatives to Participation

An alternative is to not participate in this study.

Benefits (good that may come from being in this research)

You might not benefit directly from this training or study, but what we learn from this study might help us improve First Face training for the benefit of many Tribal communities.

Costs

You will not have any costs from being in this study.

Payment

You will not be compensated for your participation in this research study.

Study-Related Injury

We do not anticipate any study-related injuries occurring as a result of this project. However, if you get hurt or get sick as a direct result of being in this study, emergency treatment will be given to you. All needed emergency care is available to you, just as it is to the general public. Any needed medical care is available to you at the usual cost. You or your insurance carrier will have to pay for any such medical care.

Voluntary Participation

Taking part in this study is voluntary. If you do not take part you will not be punished or lose benefits that you have the right to receive. If you choose to take part and then decide to stop, tell a member of the research team. Any information collected from you before the date you leave the study will be used in the research study.

Privacy / Confidentiality

There are laws (state and national) that protect your information to keep it private. We follow those laws. Your identity and study data will be kept confidential, except as required by law.

We will follow these guides:

- We will store your identifying information in a secure location and keep it separate from your data in our databases.
- We will not include any information that could identify you in any publication or report.
- We will remove all of your identifiable information from our study records 10 years after the study has been completed.

We will make every effort to keep your information private, but we cannot guarantee it. The Portland Area Institutional Review Board (IRB) is responsible for protecting the safety and welfare of people who take part in research studies in this region. IRB staff may ask to look at any research records to make sure the study team is following the laws and rules to protect you. Certain government agencies, including the Office for Human Research Protections, may also look at records that identify you.

Sometimes, we are required to share your study records with others, too, including:

- Other researchers conducting this study;
- The study sponsor and any companies that the sponsor uses to oversee, manage, or conduct the study.

If any of these groups ask to look at your information, then we cannot prevent it from being shared. Once information is shared, we cannot guarantee any further confidentiality and privacy.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Certificate of Confidentiality

A Certificate of Confidentiality (CoC) issued by the NIH covers this research. A CoC helps protect your identifiable information. A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research. Specifically, no one can be forced to share your identifiable information for a lawsuit and your information can't be used as evidence even if there is a court subpoena. If you consent, your information could be shared for other scientific research.
The CoC does not prevent some disclosures:

- The researchers can't refuse requests for information from those funding this research. Our funder, the National Institute of Health (NIH) may need information to assess this project.
- You can still share information about yourself. You can also freely discuss your involvement in this research.
- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.

Period of Authorization

Your authorization on this research project will expire 10 years after completion of data gathering for the study. If you change your mind and want to withdraw your authorization, please tell a member of the study team. If you withdraw your authorization, you may no longer be allowed to participate in the study described in this form.

Getting Help (Contacts)

If you have questions about this study, please ask a member of the study team. Some questions people might have include:

- What are the risks and benefits of being in this study?
- What other choices are available?
- What are my rights as a research participant?
- What should I do if I feel pressured to take part in this study?
- How is my information used in this study?
- How will my information be protected?

Contact the study team for answers to any study-related questions or if you get hurt or sick as a result of being in this study. This is how to contact us Monday to Friday during regular business hours:

Dr. Melinda Bowman (509) 795-8342

If you have questions about your rights as a study participant, please contact the Portland Area IRB Chair:

IRB Chair - Rena Macy Telephone: 877-664-0604

Confirmation from Person Obtaining and Documenting Consent

I, the study participant, have read this form or it has been read to me. I understand my part in this study and have had my questions answered to my satisfaction. I agree to take part in this research study.

_____ _____

Participant's Signature Date

I have informed the study participant, _____ of:

Participant's Printed Name

- The procedures, purpose, and risks related to participation in the above-described study;
- How his/her information may be used, shared, and reported, and;
- His/her privacy rights.

_____ _____

Signature of Researcher Obtaining Consent Date

_____

Printed Name of Researcher Obtaining Consent