



Official Title: Assessing Cultures of Recovery in Tribal Communities – Research Core – Training Evaluation

Brief Title: First Face Training Evaluation in Tribal Communities

Document: First Face Evaluation Study Informed Consent Form

Date: July 21st, 2023



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. You may take this form home with you to discuss with family or friends before you decide whether to be in this research study.

Study Title: *First Face Training Evaluation Study*

Your name (Participant):

Today's Date:

Name of Principal Investigators: Martina Whelshula, Ph.D., Debi A. LaPlante, Ph.D., and Sarah E. Nelson, Ph.D.

Name of Co-Investigator(s): Eric R. Louderback, Ph.D.

Consent form version date or number: v1.0

Name and telephone number of study contact to contact with questions:

Hannah Tomeo (Research Coordinator)
info@firstface.org (509) 795-8344

Approving IRB: Portland Area IRB

Study Sponsor(s): National Institutes of Health

Key Information

- You are invited to take part in a study called “*First Face Training Evaluation Study* (the *First Face Study*).
- Taking part in this study is voluntary. You have the choice to take part or not. You may leave the study at any time for any reason.
- If you choose to take part in the study, you will participate in the *First Face Training*, which will be offered in your community. You will receive the training either this summer or in 6 months. You will also be asked to complete surveys before the training and after the training. You will be asked to complete five 15-30 minute surveys over the course of two years. These surveys will help us evaluate the *First Face Training*.
- You will receive up to \$180 in gift cards for your participation.
- You might have moments during the training or surveys when you feel stressed or anxious. Despite strong efforts to maintain your confidentiality, what you say in the training or 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 training or study, but we hope the training will provide you with knowledge and skills to help individuals in your community experiencing mental health crises.
- An alternative is to not participate in this training or study.

Introduction

You are invited to take part in a research study done by Dr. Martina Whelshula, Ph.D., Dr. Debi A. LaPlante, Ph.D., and Dr. Sarah E. Nelson, Ph.D., 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. We will give you a copy of the signed form. Please keep your copy for your records. It has information, including important names and telephone numbers, for future reference.

We will tell you about new findings that may cause you to change your mind about being in this study.

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 in 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.

To evaluate *First Face*, this study will include two groups – people who take *First Face* training this summer, and people who take the *First Face* training 6 months later. We have two groups so that we can compare the group that takes the training first to the group that has not yet taken the training. People in both groups will complete surveys before and after training. 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.

Approximately 700 participants will be in this study across seven Tribal Nations in Washington, Oregon, and Idaho.

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 live and/or work on one of the seven reservations where we are conducting these trainings.

To take part in this study, you must meet the following criteria:

- Live or work in one of the communities of the Coeur d'Alene Tribe, Confederated Tribes of the Colville Reservation, the Confederated Tribes of the Umatilla Indian Reservation, the Kalispel Tribe of Indians, the Kootenai Tribe of Idaho, the Nez Perce Tribe, or the Spokane Tribe of Indians;
- Be age 14 or older at the beginning of the study;
- Be able to attend the *First Face* training program.

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 24 months. You will attend the *First Face* training, which will take about 8 hours, either in one day, or over the course of 2 days. You will either attend that training this summer or 6 months later. You will also complete five surveys – one each at the beginning and end of the *First Face* training, and three more online at six-month and 12-month intervals. Each survey will take 15-30 minutes to complete.

Procedures (what will happen during this study)

If you decide to take part in this study, the following procedures will be done as part of the study:

- You will be randomized to either the Initial Training group or the Waitlist Training group.

- You will participate in the *First Face* training, either this summer, or six months later.
- You will complete five surveys, each of which is 15-30 minutes long. The surveys will ask you questions about your knowledge about mental health topics, your attitudes and beliefs about mental health, and how you feel about responding to mental health situations. You will complete these surveys on a schedule that will be determined by which group you are in.
 - The Initial Training group will complete a pre-training survey immediately before their *First Face* training and a post-training survey immediately after training. They will also complete surveys online six, twelve, and twenty-four months after training.
 - The Waitlist Training group will complete an initial survey online this summer, and then, six months later, will complete a pre-training survey immediately before their *First Face* training and a post-training survey immediately after training. They will also complete surveys online six and eighteen months after training.

Collection of identifiable private information or identifiable biospecimens

The only identifiable information we will gather from you will be contact information so we can get in touch with you to attend the *First Face* training and complete surveys. The information that you provide in the surveys will be identified by a participant ID number that will be linked to your contact information. In some surveys, we might include your name in addition to your participant ID number so we can make sure we identify you correctly. Only the study team will have access to the surveys and contact information.

When we enter the information from the surveys into our database, we will not include any identifying information. We will store your survey data and your identifying information separately. All digital data will be stored and accessed on a password-protected digital drive that is only accessible to the researchers. Paper copies of surveys and consent forms will be stored in locked file cabinets at the Healing Lodge of the Seven Nations and/or Cambridge Health Alliance. Online surveys will be administered using a survey provider approved by the National Institutes of Health, the Qualtrics XM 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.

Your information collected as part of the research might be used or distributed for future research studies. No identifying information will be shared, and data will not be shared without permission from the Tribes involved in this project.

Possible Risks, Discomforts, Side Effects, and Inconveniences

We anticipate that there will be limited risk to participants associated with this voluntary research study. The only activities involved are the *First Face* training and a series of surveys. The following are possible risks and side-effects associated with your participation in this study:

- You might have moments during the *First Face* training when you feel stressed or anxious.
- Some of the questions that you will be asked 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 training or 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 we hope the *First Face* training will provide you with knowledge and skills to help individuals in your community experiencing mental health crises. What we learn from this study might help others in the future by raising awareness, reducing stigma and enhancing community members' ability to recognize and help when encountering or experiencing mental health crises and addiction in their communities.

Costs

You will not have any costs from being in this study. The *First Face* training program and surveys will be provided to you at no cost.

Payment

You will be compensated for your participation in this research study. If you attend the *First Face* training and complete all five surveys over the course of 2 years, you will receive \$180 in gift cards. Below, we provide a more specific breakdown of compensation by survey.

If you are part of the Initial Training group, you will receive:

- A \$20 gift card for completing the first survey (baseline survey) immediately before the *First Face* training;
- a \$20 gift card for completing the second survey (post-training survey) immediately after the *First Face* training;
- a \$40 gift card for completing the third survey (6-month follow-up survey) six months after the *First Face* training;
- a \$40 gift card for completing the fourth survey (12-month follow-up survey) twelve months after the *First Face* training;
- a \$60 gift card for completing the fifth survey (24-month follow-up survey) twenty-four months after the *First Face* training.

If you are part of the Waitlist Training group, you will receive:

- A \$20 gift card for completing the first survey (pre-baseline survey) six months before the *First Face* training;
- a \$30 gift card for completing the second survey (baseline survey) immediately before the *First Face* training;
- a \$30 gift card for completing the third survey (post-training survey) immediately after the *First Face* training;
- a \$40 gift card for completing the fourth survey (6-month follow-up survey) six months after the *First Face* training;
- a \$60 gift card for completing the fifth survey (18-month follow-up survey) eighteen months after the *First Face* training.

You will only be paid for each survey that you complete. You will be given your payment via online gift cards or physical gift cards that can be picked up at the *First Face* training and/or mailed to your home address.

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.

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:

Email: info@firstface.org

You can also call the study team if you have an urgent question or concern:

Hannah Tomeo (Research Coordinator) 509-795-8344

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

IRB Chair - Thomas Weiser: 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.

The study participant has been provided with a signed copy of this form.

Signature of Researcher Obtaining Consent

Date

Printed Name of Researcher Obtaining Consent