

I. Background & Rationale

With funding from the National Institutes for Health, we created First Face for Mental Health. First Face is a culturally-appropriate community-based mental health training that prepares trainees to provide assistance to someone having a mental health crisis. The more community members within Tribal nations who are trained in a culturally sensitive program to provide support to youth in recovery and members struggling with mental health problems or crises, the better positioned that community is to create a supportive recovery environment for its youth. We are in the process of launching First Face trainings and evaluations among several Tribal communities. Additionally, we will be training staff from the Healing Lodge of the Seven Nations (HL) in the First Face program. This particular application concerns the evaluation of First Face training among HL staff.

II. Aims & Hypotheses

Our goal is to evaluate the impact of First Face training on the trainees. We hypothesize that trainees will demonstrate: (1) gains in their knowledge of mental health/addiction issues, (2) gains in their confidence in providing first aid to people experiencing mental health/addiction crises, and (3) decreases in stigma toward people experiencing mental health/addiction issues, from pre-training to post-training and will retain these improvements until a 3-month follow-up. This evaluation will provide evidence about the effectiveness of the First Face training program among workers in a healthcare setting and guide future modifications and expansions of the curriculum.

III. Research Plan

A. Study Design

This study will use a longitudinal research design to assess the direct effects of the First Face training.

B. Study Location

This study will take place at the Healing Lodge of the Seven Nations (HL), a residential treatment facility located in Spokane, WA. Only HL staff will participate in the evaluation; no residents will be involved.

C. Funding

This study is part of the Capacity Building Core component of “Assessing Cultures of Recovery in Tribal Communities,” a Native American Research Centers for Health (NARCH) Center grant awarded to us through the National Institutes of Health (#S06GM146095). As the funder, NIH does not provide IRB oversight but will require us to submit our letter of approval once the IRB protocol is approved by the PA-IRB.

D. Collaboration

This study is a collaboration between researchers at the Healing Lodge of the Seven Nations and Cambridge Health Alliance. Because all activities will take place at the Healing Lodge, we are requesting that the Portland Area IRB serve as the reviewing IRB for this study. We will ask the Cambridge Health Alliance IRB to cede review to the Portland Area IRB.

E. Subject Populations

This study will involve HL staff members.

F. Recruitment

We will work closely with HL leadership to determine the timing of each First Face training session, minimizing any disruptions to the delivery of services. Training will take place in small groups at the Healing Lodge, led by the HL’s five Training & Research Coordinators (TRCs; Ms. Barlow, Ms. Jones, Ms. Bird, Ms. Campbell, and Ms. Bliesner). All TRCs have been trained in human subjects research/good clinical practice. They are supervised at the HL by Dr. Bowman and Dr. Zuckerman. We anticipate that HL leadership will make First Face training mandatory for all staff; however, participating in the evaluation will be optional. During 2024, the TRCs will train current HL staff.

There will be a \$20 gift card for completing the 3-month follow-up assessment. The TRC names listed above are current as of this modification.

G. Informed Consent

The informed consent document will inform potential participants about the nature of the study, including all potential risks and procedures for minimizing those risks. The TRCs will explain the nature and purpose of the evaluation, including its voluntary nature. They will be available in-person to answer any questions about it.

H. Study Procedures and Materials

We have designed our study procedures to minimize the potential for perceived coercion/undue influence and the risks associated with a breach of confidentiality.

When they enter the training room, participants will be given a letter-sized mailing envelope that includes an informed consent form and the pre-training and post-training surveys. After participants settle in, the TRCs will explain the nature and purpose of the evaluation, including all major points included in the informed consent form. Before the training begins, participants will be given ample time and space to read/sign the informed consent statement and complete the pre-training survey. The consent statement will ask for participants' email addresses, for the purposes of contacting them later. The TRCs will tell them that they are free to leave the documents blank, without consequence. The TRCs will remain at a respectful distance during this time so as to minimize any appearance of coercion. Participants will be instructed to return the consent form and pre-training survey (completed or blank) into the envelopes. After the training is complete, the TRCs will use the same process to administer the post-training survey. Then they will collect the envelopes and bring them to their private office space at the HL and store them in locked file cabinets. There are no alternative procedures.

Three months after the staff training is complete, a TRC will email all participants a link to an electronic survey which includes the 3-month follow-up questions. The email will be sent to the HL addresses collected on the consent forms but will use blind carbon copy. The follow-up survey will be hosted on a web-based survey platform attached to the co-PI's

Cambridge Health Alliance account. The survey will ask for participants' names, for the purpose of connecting 3-month follow-up surveys with pre- and post-training surveys.

Dr. Gray will download the 3-month follow-up survey dataset from Qualtrics. She will upload it to the Division on Addiction's HIPAA-compliant Google business drive and permanently delete the locally saved/downloaded file. Working within the Google drive version, a TRC will add new columns for participants' pre-and post-training survey data. Using participants' names as a linking identifier, the TRCs will enter in all pre- and post-survey data. When all data entry is complete, the TRCs will delete the participant name column from the dataset. Then, the TRCs will separate consent forms from completed pre-training/post-training surveys, leaving no way to re-connect identifiers to survey data. The TRCs will store these forms in a locked file cabinet in their HL office space.

We will provide an additional option for participants who would prefer to complete their 3-month follow-up survey using a hard copy, rather than online. Paper copies of the survey will be available in 3 locations on the Healing Lodge campus: (1) in the main administration building, in care of the receptionist; (2) in the HOPE building, in the care of the TRCs; and in the PSSD building, in care of Dr. Zuckerman. Once per month during active data collection, the Healing Lodge Executive Director will send an email blast to all employees informing them that the survey is available in these locations and encouraging them to complete it. The email will be general, rather than specific to only participants who have not yet completed their survey, because the Executive Director will have no access to individual-level data including whether participants have completed their follow-up survey. Participants who elect to complete a hard copy will get a blank copy from the designated records custodian at each location (i.e., the receptionist, the TRCs, Dr. Zuckerman), along with a sealable letter-sized manila envelope and, if necessary, a clipboard and pen. They will complete the survey, seal it in the envelope, and return it to the records custodian for safe storage until a TRC or Dr. Zuckerman can pick it up. TRCs or Dr. Zuckerman will go to these locations each day to pick up completed surveys. They will bring completed surveys to their dedicated office space in the HOPE building, where they will store and enter the data as they do for hard-copy surveys administered on the day of the First Face training.

In the text of the email inviting participants to complete their 3-month follow-up survey, and at the end of the survey itself, we will direct participants who complete their 3-month follow-up survey to go to the HOPE building and speak with one of the 6 TRCs to receive

their \$20 gift card incentive. We will retroactively provide a \$20 gift card to participants who completed their 3-month follow-up survey in the summer of 2024.

In the text of the email inviting participants to complete their 3-month follow-up survey, and at the end of the survey itself, we will direct participants who complete their 3-month follow-up survey to go to the HOPE building and speak with one of the 6 TRCs to receive their \$20 gift card incentive. We will retroactively provide a \$20 gift card to participants who completed their 3-month follow-up survey in the summer of 2024.

We will also prepare a flyer with a QR code that directs participants to the 3-month follow-up survey hosted on the Qualtrics survey platform. We will post this flyer in common areas and leave it in participants' Healing Lodge mailboxes.

To provide another opportunity for participants to complete their 3-month follow-up survey, the TRCs will host 3-5 group survey sessions. They will select an appropriate location on the Healing Lodge campus and invite participants to come and complete their 3-month follow-up survey. They will select times in consultation with department managers/human resources. The TRCs will ensure that at these group survey sessions, participants will have ample space and privacy to complete the survey. TRCs will provide gift cards immediately after participants complete and return the survey. TRCs will store completed surveys in locked cabinets in the Hope Building. They will promote these survey sessions via email. Additionally, the survey sessions will be promoted by (1) the Healing Lodge Executive Director via an all-hands email, (2) department managers during department meetings, and (3) on informational screens that appear around campus. This will ensure that participants know they can take the time to complete their surveys during work hours without experiencing any punishment. The promotions will include a reminder that completing the survey is voluntary.

We will assess changes in three domains:

1. Knowledge of mental health/addiction issues, including knowledge of the 5 "Healing Hands" steps, which are a foundation of First Face training
2. Confidence in providing first aid to people experiencing mental health/addiction crises
3. Stigma toward people experiencing mental health/addiction issues

Additionally, the post-training survey will assess satisfaction with the training and intentions to use the training. The 3-month follow-up survey will assess use of the training.

To explore potential moderators of effectiveness, we will assess participant characteristics (e.g., department, years working with at-risk youth, past mental health/addiction training). For instance, more experienced staff members might show smaller improvements in study outcomes because they have less room for growth before they complete the training.

I. Risk/Benefit Assessment

Risks. Participating in this evaluation presents psychological/social risks but no legal, financial, or physical risks. Some participants might experience discomfort or distress from answering questions. Accidental disclosure of study data presents another risk to participants.

Protection Against Risks. The consent form will assure participants that they are not required to engage in the evaluation or answer any questions that make them uncomfortable. Our procedures for data collection, transfer, and storage will ensure that there will be no security breaches. Hard copies of consent forms and pre- and post-training surveys will be stored in locked file cabinets in the Hope Building on the HL campus. Only members of the study team located at the Healing Lodge will have access to them. Subsequently the TRCs will enter data into an electronic database. Division on Addiction staff members named in this protocol will assist the TRCs with data analysis, interpretation, and dissemination. Therefore, the electronic database will be stored on the Division on Addiction's password-protected shared Google Drive, which is part of the Cambridge Health Alliance HIPAA-compliant Google business account. No publications or presentations will include potentially identifying information. In keeping with open science best practices, we might, with permission from the Healing Lodge Board of Directors, make the raw data publicly available. However, we will minimize the number of potentially identifying characteristics included in the dataset to prevent deductive disclosure. The consent form will also include a Certificate of Confidentiality section.

Potential Benefits of the Research to Participants and Others. This evaluation holds the potential to advance an intervention designed by and for Tribal communities to help their youth struggling with addiction or mental health issues. The evaluation, if positive, will

provide evidence supporting First Face's effectiveness and encourage widespread adoption. If First Face does not demonstrate effectiveness, the study will provide information about how to improve it.

Vulnerable Participants: Children. No children will be recruited into this study.

Employees. We acknowledge that the participation of Healing Lodge employees might present special concerns, particularly the potential for perceived coercion. We will take several steps to minimize perceived coercion. The consent form will assure potential participants that they are not required to engage in the evaluation or answer any questions that make them uncomfortable. The TRCs will give potential participants personal space to complete, or elect not to complete, the consent form and surveys. Because all potential participants will place their consent forms and surveys back into the provided envelope, regardless of whether the forms have been completed, it will not be obvious whether employees have elected to participate in the evaluation. Finally, potential participants will be informed that only the research team will have access to collected data.

J. Data and Safety Monitoring Plan

We consider this research to be minimal risk, with the primary risks being the potential for some emotional distress based on the training or surveys, and potential breach of confidentiality. In addition to the steps taken to protect against these risks detailed above, we will follow the guidelines set out below.

We have already obtained Resolutions supporting this work from the Healing Lodge Board of Directors and all seven Tribes that support the Healing Lodge. In addition, the Division on Addiction will be signing a Data Sharing Agreement with the HL. We will submit that agreement to the IRB as soon as it is signed. We will also submit all manuscripts to the Healing Lodge Board and the IRB to obtain approval prior to submission for publication.

We will protect participants' confidentiality by storing data securely, as described earlier in this protocol. The research team will meet weekly to review the project and data collection efforts. We have had success with this model, using technology to meet remotely across sites on a weekly basis for our previous NARCH VIII and NARCH X projects.

During data collection periods, the research team will meet weekly. During these meetings, the TRCs will have the opportunity to raise any concerns about participants' experiences in the study concerns or protocol compliance with Dr. Gray. In addition, the phone number provided for study participants to contact with concerns or questions will be monitored on a daily basis. Dr. Gray will be responsible for reporting any adverse events in a timely manner to the IRB in accordance with IRB rules and regulations. In addition, Dr. Gray will review any unexpected findings, unanticipated findings, or issues regularly with the research team so that corrective actions, if necessary, can be taken promptly. We do not anticipate that any aspect of this study will affect the safety of participants. However, if our review detects any findings or patterns that call into question the safety of the First Face Healing Lodge training evaluation, we will stop the study until these issues are resolved.