

**[UNIVERSITY/SCHOOL]
PARENT CONSENT FORM**

Principal Investigator:

Study Title:

IRB No.:

PI Version Date:

Key Information about the Study

- You are being asked to allow your youth to join a research study to help us understand how an intervention affects binge substance use in Native American youth.
- This study is a 2–4-hour long lesson with youth who use substances, and three assessments up to one-hour long each.
- Your youth can receive up to three gift cards totaling in \$75. Your decision to let your youth participate is voluntary. You may choose not to let your youth take part at all, and if you let your youth join, you may decide to quit at any time. There will be no penalty if you decide to end your youth's participation in the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to let your youth continue to be in the study.

Details about the Study

Why is this research being done?

This research is being done to test how effective a brief program is at reducing binge substance use in Native American youth ages 12-17. To understand how the program impacts youth who have a recent binge substance use event, participants will receive a lesson on binge substance use from a Life Research Program Assistant (RPA) and answer a series of questions about themselves at three different time points: when they enroll in the study, 4 weeks later, 4 weeks after that visit. These are called assessment visits, and the questions will ask about participants' substance use, family and peer relationships, and other emotions and behaviors.

We will make sure you and your youth understand all the study procedures. You should ask questions at any time. Please sign this form for your youth to join this study. We will give you a copy of this form for your records.

Who can join this study?

Your youth is being asked to join this study because they are Native American age 12-17 years old, reside on or near [Reservation], and have had a binge substance use event within the past 90 days. We expect a total of 100 youth to participate in this study.

What will happen if your child joins this study?

If your youth joins this study, we will ask you and your youth to allow a trained Life RPA to visit you and your youth at your home or another private location. There will be four study visits total – three visits to complete the assessments, and one visit to complete the intervention lesson. To test how effective the lesson is, around half of the participants will receive the lesson after the first assessment visit, and half of the participants will receive the lesson after the third assessment visit, after all the participants have enrolled in the study.

Additionally, if your youth is not already in contact with local services and resources that could be helpful to them, the RPA can also help them get connected to these services in the community. If the youth is invited to participate in the study, the lesson will be audio recorded to make sure RPAs are following correct study procedures and to accurately capture all the information youth share. Recordings will be kept confidential and stored in a secure, online database and deleted at the end of the study.

We won't report anything your youth tells us in the questionnaires or what we learn about during the visits unless we're worried your youth might hurt themselves, they might hurt someone else, or someone is hurting them. Life RPAs will make sure your youth understands all the study procedures. Your youth can ask questions at any time.

Safety Questionnaires

At the end of the visit, we want to make sure that your youth is not in danger of hurting themselves. Your RPA will give your youth a questionnaire that asks about suicidal thoughts and behaviors that they might be having. Based on your responses to the questions, we may do the following:

- If your youth seems to be at some risk for hurting themselves, we will call the senior staff person on site to review your case and develop a plan to help them. The head of the program and senior program team members will also be notified and will assist with developing the plan.
- If your youth seems to be medium to high risk for hurting themselves, we will tell the on-site senior program staff person right away. We will either set up an appointment for them right away with [Mental/Behavioral Health Service(s)].
- If your youth seems to be very high risk for hurting themselves, we will immediately contact the one-site senior staff member. A Life team member will escort your youth to the Emergency Department at the [Location] Service Unit.
- In addition, if we find out that your youth are not currently at risk for hurting themselves but did try to hurt themselves at another time while in this program, we will contact the Life Team so they can follow-up with them. We will also talk to the Life Team about whether it is a good idea for them to stay in this program.
- You will be notified and involved in the above steps if your youth is determined to be at high risk.

What are the risks or discomforts of the study?

The main burden to your youth is that they may feel uncomfortable answering the questions in the assessments, especially talking about their mental health and risky behaviors.

We hope your youth will feel more comfortable knowing our study staff are trained to discuss sensitive topics appropriately, be good listeners, emphasize the importance of confidentiality, keep your youth's information private and connect them to appropriate resources in the community. Please note, that we will not notify or disclose anything to you that your youth discloses to us during the study.

What are the potential benefits to being in the study?

Your youth's participation will benefit your community and science by helping to understand if the program can help Native American youth reduce their binge substance use.

Will your child be paid if they join this study?

Your youth can receive up to 3 gift cards, totaling in \$75, for completing the assessment visits:

Participants in RCT	
Baseline	\$15 gift card
4 weeks post baseline	\$30 gift card
8 weeks post baseline	\$30 gift card

What happens to data that are collected in the study?

To keep your youth's information private, we will assign them an ID number when they start the study. Any information we collect from them will only have this ID number on it. We will keep a separate list that links your youth's study ID number to their name. This list will be private and all information about your youth will be stored in a locked file cabinet in the office. All electronic data will be stored on computers that are password protected.

Your youth cannot be in the study unless you agree that we can use the information they provide to evaluate the study findings. No identifying information will be included with the data that is analyzed. There will be no way to identify you in any publications or study results.

Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your youth's information even if requested using legal means. It does not protect information that we have to report by law, such as abuse of the youth. The Certificate does not prevent us from disclosing your youth's information if we learn of possible harm to themselves or others, or if they need medical help.

There are a few times when we will not be able to keep your youth's information private. We may be required to give out information about your youth if the government audits us. The research team will also give out information to the appropriate local or state authorities:

- If your youth appears at risk for hurting themselves including from substance use.
- If they suspect abuse or neglect of a youth or dependent adult.
- If the team learns that your youth plans to harm someone else.

How will the confidentiality of your child's data be protected?

The interview session will be conducted in a private location of you or your youth's choosing. If you, your youth, or the RPA feel as though the location is not suitable, the session may be stopped and moved to a more private location.

What are your child's options if you do not want them to be in the study?

You do not have to allow your youth to join and participate in this study. The alternative is not to participate in the study. As needed or requested, Life RPAs will refer all individuals for care outside the study, including referrals to mental health care providers.

Will it cost you anything for your child to be in this study?

There are no anticipated costs to participate in this study.

Can your child leave the study early?

Your youth may leave the study at any time without any penalty. Please note, if your youth decides to withdraw from the study at any time, it will not affect their care they receive at [Healthcare Facility]. If you or

your youth move off-reservation or are relocated for treatment, your youth will not be expected to participate in the rest of the study.

Ending Consent

You may end your approval at any time. Information obtained and used before you end your approval will continue to be used for research. If you do not want your youth's information continued to be used for research, please let us know. If you wish to end your approval allowing your youth to participate, let us know.

What is the Institutional Review Board (IRB) and how does it protect you?

This study has been reviewed by an Institutional Review Board (IRB), a group of people including scientists and community people, that reviews human research studies. The IRB can help you if you have questions about your rights as the parent of a research participant or if you have other questions, concerns, or complaints about this research study.

What should you do if you have questions about the study, or are injured or ill as a result of being in this study?

- Call the principal investigator, [Name], at [Contact Number] if you have questions or complaints, or get sick or injured because of being in this study.
- Call or contact the [University] School of Public Health IRB Office if you have questions about your rights as a parent of a study participant. Contact the IRB if you feel you have not been treated fairly or if you have other concerns.

- The IRB contact information is:

Address:

Telephone:

Toll Free:

E-mail:

Future Contact

We would like your approval for our research team to contact you in the future. Please indicate your decision below by checking the appropriate box.

YES NO

What does your signature on this consent form mean? Your signature on this form means:

- You have been informed about this study's purpose, procedures, possible benefits, and risks.
- You understand that if your youth is asked to participate in the interview session, it will be audio recorded.
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to allow your youth to be in this study.
- You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Parent/Guardian of minor Participant

(Print Name)

Date/Time

Signature of Person Obtaining Consent

(Print Name)

Date/Time