

[UNIVERSITY/SCHOOL]
ASSENT FORM

Study Title:

Principal Investigator:

IRB No.:

PI Version Date:

Key Information about the Study

- You are being asked 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.
- You can receive up to three gift cards totaling in \$75.
- Your decision to participate is voluntary. You may choose not to take part at all, and if you join, you may decide to quit at any time. There will be no penalty if you decide to end your participation in the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.

Purpose of the study

We want to tell you about a research study we are doing. Research allows us to collect information from people to help us answer questions about health. We would like to find out more about how to best help Native American youth reduce their use of alcohol and drugs. All information collected will help us understand how effective this program is at reducing binge substance use in youth ages 12-17.

Why you are being asked to join the study

You are being asked to join the study because you are a youth between the ages of 12-17, reside on/near [Reservation], identify as Native American, and had a recent binge substance use event in the past 90 days. We hope to include about 100 youth in this study.

Study procedures

If you agree to join this study, you will be asked to participate in a brief lesson with our Research Program Assistants from the Life team. During this lesson, you may learn about skills that will help you reduce your binge substance use. An RPA will also ask you a series of questions during three different assessment visits: when you enroll in the study, 4 weeks later, and 4 weeks after that visit. The questions will ask about your substance use, family and peer relationships, and other emotions and behaviors. You may be offered the lesson after the first assessment visit, or you may be offered the lesson later after the third assessment visit.

If you join this study, we will assign you an ID number and then any information we collect will have this ID number on it. This way, when we look at data, we don't know the participant's name right away. During the lesson, the RPA will audio record the visit and save it with your ID number, not your name. Then we can listen to the recordings later and make sure RPAs are following correct study procedures and accurately capturing all the information the participants share. Recordings will be kept confidential and destroyed once quality

assurance forms are completed. Transcripts will be de-identified (so they are not attached to your name), stored in a secure, online database, and deleted at the end of the study.

We won't report anything you tell us in the lesson or assessment visits unless we're worried you might hurt yourself, you might hurt someone else, or someone is hurting you. RPAs will make sure you understand all the study procedures. You should ask questions at any time. You might sign this form to join the study.

Safety Questionnaires

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

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

Risks

Some of the questions we will ask may make you uncomfortable. You may skip any questions you want and take your time thinking about your responses. We will keep your answers private and will not share them with your parent/guardian.

We hope you will feel more comfortable knowing that our study staff are trained to be good listeners and are there to help you.

Benefits

We hope to learn about how helpful this lesson is, so that it could help other Native youth and adolescents who struggle with alcohol and/or drug use issues.

Payment

You will receive a gift card for each assessment visit you complete. You could earn up to \$75 in gift cards if you complete all three assessment visits:

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

The Life staff will not be responsible for lost or stolen gift cards, and you will not receive another gift card should it be lost or stolen.

Voluntary participation

You do not have to join this study. It is up to you. You can say okay now, and you can change your mind later. All you need to do is tell us. No one will be mad at you if you change your mind.

Do you have any questions?

If you want to join this study, please sign your name. You will get a copy of this form to keep for yourself.

(Sign your name here)

(Date)

(Signature of Person Obtaining Assent)

(Date)