

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

**Principal Investigator:**

**Study Title:**

**IRB No.:**

**PI Version Date:**

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**Key Information about the Study**

- You are being asked to allow your youth to participate in a research study to help us understand binge substance use in Native American youth.
- This study is a 2–4-hour long review of a lesson.
- Your youth’s participation will help us understand if the lesson needs any changes before the final part of the research study.
- 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 adapt a brief program to reduce binge substance use for Native American youth ages 12-17. To better understand how the program will be delivered with youth with recent binge alcohol use, we want study staff to be familiar with the lesson components and language.

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 a recent binge alcohol use event reported to the surveillance system. We expect a total of 10 youth and young adults 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 Research Program Assistant to visit you and your youth at your home or another private location. This visit will occur once for 2-4 hours.

During this visit, the Life Research Program Assistant will review a lesson with your youth that teaches life skills and coping strategies. 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.

We won't report anything your youth tells us in 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. Please sign this form for your youth to be able to join the study.

**What are the risks or discomforts of the study?**

The main burden to your youth is that they may feel uncomfortable reviewing the lesson, 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?**

our youth's participation will benefit your community and science by helping to understand how the program, can help Native American youth. We will use this session to make any needed adaptations this program so it can be offered to youth in the community to help reduce their substance use.

**Will your child be paid if they join this study?**

Your youth will not receive any money if they join this study.

**What happens to data that are collected in the study?**

Data will not be collected during this phase of the study.

Regardless of the phase, youth's 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 curriculum 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 to 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 Unit(s)]. 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], and [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**

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Signature of Parent/Guardian of minor Participant

(Print Name)

Date/Time

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Signature of Person Obtaining Consent

(Print Name)

Date/Time