

Date: 1/18/2023

National Clinical Trials #: NCT04617938

Study Title: Development and Implementation of a Culturally Centered Opioid Prevention Intervention
for American Indian/Alaska Native Young Adults in California

TACUNA: Traditions and Connections for Urban Native Americans

Consent Form

We are asking about 370 young adults in California to be in our project. If you take part, you could earn up to \$310! After we review this information, we will ask if you want to be in project.

I. WHAT IS THIS ABOUT?

Native American organizations in your community are taking part in a research project with UCLA and RAND, a non-profit, nonpartisan research organization. The National Institute on Drug Abuse funds this project through the Helping to End Addiction Long-term (HEAL) Initiative. This project is focused on testing some new programs about opioid use for American Indian/Alaska Native (AI/AN) young adults. We want to see how people like the TACUNA Groups, Wellness Gatherings and Opioid Education Groups and whether coming to these gatherings and groups helps people make healthy choices.

II. WHAT WILL WE ASK YOU TO DO?

You will be asked to:

1. **Complete four surveys:** Surveys will take approximately 60 minutes to complete. Questions will ask about your age, gender, AI/AN heritage, cultural activities, your family and your social network. We will also ask you to tell us your opinions about and experiences with different things including alcohol, marijuana, opioids and other drugs, sexual behavior, and mental and physical health. You'll complete one survey now, one in 3 months, one in 6 months and one in 12 months. You'll be paid \$40 for the 1st survey, \$60 for the survey in 3 months, \$80 for the survey in 6 months and \$100 for the survey in 12 months.
2. **Complete a locator form** where you'll provide us with basic contact information like your phone number, address and email address so we can contact you about project activities and surveys, or any future projects you may be interested in.

Participants will be randomly assigned (like a coin toss) to one of two groups. You'll be asked to either:

1. **Come to (virtual) TACUNA groups and a Wellness Gathering.** Participants selected for this part of the project will be asked to come to a 1-hour group meeting once a week for 3 weeks. Each meeting will have some group discussion about opioids and other drugs and making healthy choices and some cultural activities, such as digital storytelling and cooking. Participants will also be asked to attend a Wellness Gathering, a cultural event where we'll provide entertainment and information on healthy living. You'll be paid \$30 if you attend all 4 sessions. Or,
2. **Come to a (virtual) Opioid Education Workshop.** Participants selected for this part of the project will be asked to attend a 1-hour workshop where we provide information on opioids. You'll be paid \$10 for attending.

III. COSTS

There is no charge for being in the project.

IV. BENEFITS

We hope the project will help us learn more about what AI/AN young adults think about alcohol, marijuana, opioids and other drugs, the choices they make about use of these substances, and whether coming to the groups or education workshop can help people make healthy choices.

V. RISKS

Some survey questions may make you uncomfortable, but you can skip any questions that you don't want to answer. There is also the risk that someone could find out your answers on the survey; however, we have several ways that we will keep your answers safe. At this point, we do not know how well the groups or workshop will work to prevent opioid use. This project will help us understand that.

VI. CONFIDENTIALITY

We want you to answer the survey questions honestly, thus, the research team will keep your answers completely private. The research team will also keep what is said at the TACUNA groups, the Wellness

Gatherings and the Opioid Education Workshop confidential, and use this information only for research purposes. The groups and workshop will be audio recorded for training so that we make sure the group leaders covered the correct information. [For virtual groups: Groups will be conducted on ZoomGov, a RAND approved platform. The audio recording and a list of attendee names or phone numbers will be pulled from the Zoom cloud, entered into a secure RAND computer and deleted from the cloud.] We will ask you not to use any names on the recordings. We will destroy all recordings at the end of the study. To help keep your information private, we have a Certificate of Confidentiality from the National Institutes of Health. With this certificate, the researchers cannot be forced to provide information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding. The researchers will use the certificate to resist any demands for information that would identify you, except:

- 1) If we need to protect you or others from harm. An example of this is if you want to hurt yourself or others. In that case, we will give information about you to others that is needed to protect you or others from harm.
- 2) If you tell us about the abuse of a child or of an elderly person. In that case, we must report it to a supervisor, who may report it to the authorities.

VII: DE-IDENTIFIED DATA SHARING

The study sponsor, the National Institute on Drug Abuse, requires that we share your de-identified data with other researchers to help learn how to prevent opioid use and misuse. Project staff will protect your personal information so no one will be able to connect your responses with any information that identifies you (names, contact information). Any personal information that could identify you will be removed or changed before any data files are shared with other researchers or results are made public. Also, tribal affiliations will not be included with shared data. This is referred to as de-identified data.

Your de-identified data will be protected, following laws that protect the use of health information, and studied only for health research purposes. Your de-identified data may be used in the following ways:

- To understand how opioid use is developed and prevented.
- Combined with data from other studies to help our understanding about opioid misuse prevention and advance science and public health.
- Shared with researchers participating in a group of 10 NIDA-funded studies on ways to prevent opioid misuse. For example, these researchers may compare data across studies to look at how substance use changes over time, look at costs of different interventions, or answer other research questions.
- Publish summaries of results in scientific journals, on clinicaltrials.gov, on the internet or at meetings so that other researchers may learn about this project. Your name or any other data that identifies you will not appear in any of these summaries or publications.
- After this project is finished, the data will be stored at a highly secure data library to be shared with researchers more widely who may analyze the data to answer other questions about things like use of alcohol or marijuana. Before sharing any data with these other researchers, it will be made even harder to identify who participated. For example, information regarding where data were collected may be removed.
- Share it with regulatory agencies to help to make de-identified research data more available to researchers.

☐

I would like to opt-out. I do NOT want my de-identified data shared.

VIII. BEING PART OF THE PROJECT

You do not have to be a part of the project if you do not want to. Your choice about being in this project will not change any care that you get from any Native American organization in your community.

IX. WHO IS LEADING THE PROJECT?

Dr. Elizabeth D'Amico at RAND in Santa Monica and Dr. Daniel Dickerson at UCLA are leading the project. If you have any questions or concerns about the project, please call Dr. D'Amico at 1-800-447-2631 x6487.

X. IF YOU HAVE QUESTIONS ABOUT YOUR RIGHTS AS A PARTICIPANT

If you have questions about your rights as a research participant or need to report a research-related injury or concern, you can contact RAND's Human Subjects Protection Committee toll-free at (866) 697-5620 or by emailing hspcinfo@rand.org. If possible, when you contact the Committee, please reference Project #2019-0477.

X. CONSENT

Do you understand the information I've just read you? [INTERVIEWER: answer any remaining questions]

Do you agree to take part in this project?

1. Yes
2. No [terminate interview]