

Informed Consent Form

TITLE: Community Randomized Trial in the Cherokee Nation: Connect and CMCA for Preventing Drug Misuse Among Older Adolescents

NCT NUMBER: NCT04839978

IRB APPROVAL DATE: March 30, 2020

DATE

Dear Participant:

You are invited to be part of a study about young people and their actions. You are being asked to participate because of your age and your school agreed to be in this study. Please read this form as it is read aloud and ask any questions you may have before agreeing to be in this study. We would like to tell you everything you need to think about before you decide whether or not to take part in the study. It is entirely your choice. If you decide to participate, you can change your mind later on and drop out of the study.

The money for this study comes from a federal grant from the National Institute on Drug Abuse (NIDA) to the leaders of this study, Dr. Kelli Komro at Emory University and Ms. Juli Skinner and Dr. Terrence Kominsky with Cherokee Nation Behavioral Health.

Half of the participating schools were randomly selected (like tossing a coin) to receive drug prevention programs and half to serve as comparisons and receive the programs in three years. We do this so that we can find out if the programs work. Therefore, the study is called a clinical trial. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. law. This Web site will not include information that can identify you. At most the Web site will include a summary of the results. You can search this Web site at any time.

In all schools, people your age will be asked to complete a survey. One purpose of this study is to find out about feelings, actions, and problems young people sometimes face. Another purpose is to find out about programs that might be helpful to young people in keeping them healthy and safe. If you agree to be part of the study, we would ask you to complete a survey now and two times a year for the next 3 years. This survey will take about 15 to 20 minutes. You will be paid \$5 for each survey you participate in during the next 2.5 years and \$20 for the last survey which will be sent to you after high school.

Your answers to this survey are kept private. We will do our best to make sure no one outside the study knows you are part of the study. We will take your name off information that we collect from you during the study. We will give your information an ID number, so that no one can identify you. Because of this ID number there is a small risk of invasion of privacy due to the link with your name. Your name and study ID will be kept in separate electronic, secured files so that your name will not be kept with your answers. Your answers will be kept private. Keeping this private means that your parents, teachers, and friends will NOT see your answers. One of the reasons we do this is so that you will feel free to answer questions honestly.

There are people who make sure the study is run the right way. These people may see information that identifies you. They are the Office for Human Research Protections, the Emory Institutional Review Board, the Cherokee Nation Institutional Review Board, and the Emory Office of Research Compliance. Study funders may also look at the study records. A study number rather than your name will be used on study records wherever possible. When we share the results of the study in presentations or published papers, we will not include your name or anything else that could identify you. The survey does not ask questions about someone hurting you or you hurting yourself. However, laws require that we tell someone who could help if we learn someone hurt you or that you might hurt yourself or someone else.



We have obtained a Certificate of Confidentiality for this study. This means that if Emory or Cherokee Nation received a subpoena (an order from a judge) for study records that identify you, we would say no, and the Certificate gives us this authority. The Certificate does not prevent you or someone other than you from disclosing your information. The Certificate also does not prevent Emory or the Cherokee Nation from sharing information about you because:

- We find out that child abuse has taken place
- We find out information to prevent immediate harm to you or others
- We share information to the study funder as part of the research

Some of your information may be placed into public databases for other researchers to use. Anything we share would only use a code number instead of your name. In addition to not including your name, researchers will need to sign data use agreements before using or seeing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot promise that your answers could not be linked back to you.

You do not have to complete this survey if you don't want to, but taking part in our research is very important. Either way, your decision will not affect your class grade, or current or future relations with Emory University or the Cherokee Nation. If you decide to do the survey, you are free to stop at any time or skip any question you do not feel comfortable answering. If you decide not to complete the survey, please study quietly while others complete the survey.

Once the study is finished, we will send you a summary of all of the results of the study and what they mean. We will not send you your individual results from this study. Thank you for your help. We hope that you will enjoy taking part in the survey. We will continue to bring or send the surveys to you every few months. You may ask questions you have now. If you have questions later, you may contact anyone below.

Contact Information

If you have questions about this study, your part in it, your rights as a research participant, or if you have questions, concerns or complaints about the research you may contact the following:

Dr. Terrence Kominsky, Cherokee Nation Co-Principal Investigator:
[REDACTED] or toll-free at [REDACTED]

Sohail Khan, Director of Health Research & Cherokee Nation Institutional Review Board Chair:
918-453-5000 ext. 5187 or by email at irb@cherokee.org

Emory Institutional Review Board:
404-712-0720 or toll-free at 877-503-9797 or by email at irb@emory.edu

Sincerely,

Terrence K. Kominsky, Ph.D.
Coordinator, Behavioral Health Research and Evaluation
Cherokee Nation Behavioral Health

Kelli A. Komro, MPH, PhD
Professor
Emory University School of Public Health