Community Randomized Trial in the Cherokee Nation: CONNECT and CMCA for Preventing Drug Misuse among Older Adolescents

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Trial Phase
9/01/2020 – 8/31/2024

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Study sites:
Cherokee Nation
Emory University

Proposal for Research Protocol for Trial Phase

I. Overview/Introduction

The national public health opioid crisis has disproportionately burdened rural white populations, and disproportionately burdened American Indian populations. Therefore, the Cherokee Nation (CN) and Emory University public health scientists have designed an opioid prevention trial to be conducted in at-risk rural communities in the CN (in northeast Oklahoma) with white and American Indian adolescents and young adults. Our goal is to implement and evaluate a theory-based, integrated multi-level community intervention designed to prevent the onset and escalation of opioid and other drug misuse. We propose a community randomized trial building directly on the success of our most recent previous trial, which demonstrated that our intervention effectively reduced alcohol and other drug use among American Indian and other youth living within the CN. Two distinct intervention approaches—community organizing as implemented in our established CMCA intervention protocol, and universal school-based brief intervention and referral as implemented in our established CONNECT intervention protocol—will be expanded and integrated to further enhance effects in preventing and reducing opioid misuse. The CMCA and CONNECT interventions were originally designed to target adolescent alcohol use, but nevertheless showed significant beneficial effects also on use of other drugs, including prescription drug misuse. The proposed study will: (1) further improve the design of the interventions with increased focus on opioids, (2) test the expanded, integrated versions in a community randomized trial, and (3) design and test new systems for sustained implementation within existing structures of the Cherokee Nation. Building upon the extant prevention science evidence, our study will respond to a gap in evidence concerning opioid misuse prevention among at-risk adolescents transitioning to young adulthood among American Indian and other rural youth. Our previous trial, conducted in partnership with the Cherokee Nation, ended with youth attaining age 18; the proposed new trial will additionally advance the science regarding strategies to engage young adults as they transition beyond high school.

II. Methods and Study Population

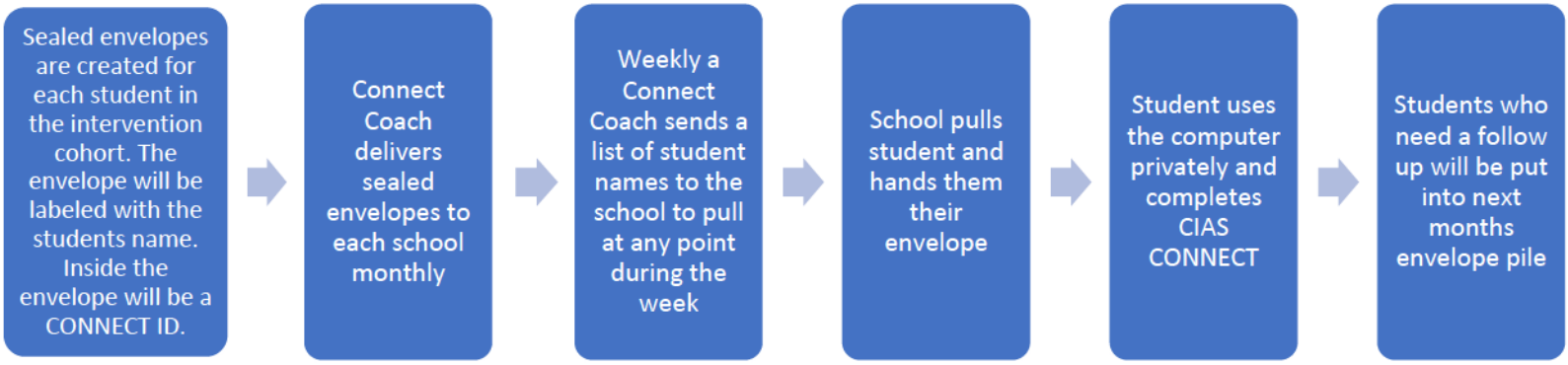
Sample

Sixteen to twenty-four high schools and surrounding towns within the 14-county Cherokee Nation reservation in northeast Oklahoma will be purposively selected based on school and community characteristics (e.g., size of high school, distance between towns, existing prevention program), stratified by risk profile, and randomly assigned to study condition: (1) preventive intervention or (2) delay-program control. In-person meetings will be conducted with project leadership and school leadership (school district superintendents and high school principals). PIs will present study details and invite the school leadership to participate in the study and to sign a cooperative agreement form. If the high school within a selected town refuses to participate, a replacement town will be selected from within risk strata. Given our recruitment history, we anticipate a very high participation rate—our recent prevention research project with the Cherokee Nation resulted in a 100% school participation rate.

Prevention Program Overview

School district superintendents and high school principals will be asked to sign cooperative agreement forms to participate in the study. As with our previous school-based projects, school-based screening, brief intervention and referral (CONNECT program), conducted by Cherokee Nation Behavioral Health counselors, will be treated as part of the participating schools' prevention programs. According to Oklahoma State statute (Stat. tit. 63 § 2602. Right of self-consent) a minor may consent to services for the prevention, diagnosis and treatment of drug and substance or alcohol abuse treatment. In addition, the Oklahoma Department of Public Health trains school nurses to provide health education and counseling to help prevent tobacco use, alcohol use, substance abuse, and other health related issues. The CONNECT school-based prevention program is consistent with the laws and standards of practice in Oklahoma. Cherokee Nation Behavioral Health (CNBH) youth services provides a central hub connecting youth and their families to programs, resources and services. The CNBH CONNECT coaches will introduce and support the CONNECT program. Each semester, a computer-based CONNECT screening and brief intervention will be implemented universally, to reduce potential stigma and to reinforce drug-free norms among all students. Universal screening avoids contributing to harmful, negative stereotypes likely to result from singling out students. The computer-based universal screening and brief intervention will be supported by either one or two Connect Coaches. As originally planned, follow-up of moderate to high-risk youth will be conducted by a Connect Coach through Zoom, other electronic communication, or in-person visits, with referral to Cherokee Nation or community services if deemed necessary.

The Computerized Intervention Authoring System (CIAS), an NIH-funded non-commercial research resource that allows development of interactive and tailored digital health interventions, will be used to develop the computer-based screening and brief intervention. The CIAS system was previously used to develop and test a computer-based alcohol and marijuana brief intervention with motivational interviewing (CBI) for school-based health centers and was found to be as effective as a nurse practitioner-delivered brief intervention (NBI) (Gryczynski et al., 2021; R01DA036604, PI Gryczynski). There were no significant differences between NBI and CBI on any outcomes, including marijuana use, marijuana-specific problems, alcohol use, binge drinking, alcohol-specific problems. Gryczynki has given us full access and permission to adapt the program for our needs, facilitating rapid development of an effective computerized version of screening and brief intervention. Students will be given a personal CONNECT ID number to access the computer-based brief intervention on a project computer, which will be set up in a private location with the schools. No personal identifying information will be entered into the computer or brief intervention program. A flow chart showing the implementation details is below. This process allows all collected CONNECT screening data to be stored in a deidentified manner. The school personnel will not be able to access any data entered into the CIAS system. We will work with each school to troubleshoot any implementation/logistic problems throughout the intervention period.



The community-level intervention Communities Mobilizing for Change and Action (CMCA) will involve educating and organizing of adult volunteers and consent will be assumed by their participation. We will provide trainings and tools, including Family Action Kits, to support local families, community organizations and citizens, including information on national and local opioid and other drug use, evidence-based policies, programs and practices, and how to motivate and create family and local action for drug prevention.

The intervention will be further enhanced by including Cherokee Nation award-winning multi-media suicide prevention strategies adapted for drug use prevention.

The evaluation of the prevention programs will be accomplished through self-report surveys of a cohort of high school students followed over three years, from grade 10 (ages 15-17) to the year following high school graduation (ages 18-20). A pilot survey will be administered in the study schools using all approved protocols in grade 9. The main outcome analysis will include baseline (fall of 10th grade) through spring of 12th grade surveys. A secondary outcome analysis will include the six-month follow-up survey conducted six months post on-time high school graduation.

Recruitment Procedures
All 10th grade students enrolled in the participating study high schools will be eligible to participate in the study. As a universal preventive intervention, and given the need for a community-wide representative sample, there are no exclusionary criteria. Beginning in 10th grade, a cohort of high school students will be asked to participate in a brief, 20-30-minute, web-based survey on health behaviors two times per year. The survey will be administered using REDCap or Qualtrics on cellular-connected project tablets and implemented during homeroom, a class period, lunch period, or at

another time convenient to each school and participant. All data will be encrypted as soon as it is entered and transmitted to a central server at Emory University. No school personnel will be involved in any survey administration tasks, avoiding any potential risks and biases that could accrue from the involvement of school personnel in survey administration.

All 10th grade students in all participating high schools will be recruited. Participating schools will provide the researchers with a list of the most current home addresses and telephone numbers for all students in the participating high schools. Parent consent letters will be sent home by Emory University and the Cherokee Nation, describing the study and its importance and providing a toll-free and local telephone number that parents/guardians can call with questions or concerns. In-person visits will be made when requested or if the parent is unavailable via phone. Parents will be asked to respond by returning an addressed postage-paid postcard or calling Cherokee Nation Behavioral Health using toll-free telephone numbers, if they refuse permission for their son or daughter to participate. Also, each adolescent/young adult participant will be given the opportunity to decide not to participate, and may withdraw their participation at any time. Students will be provided $5 for each biannual survey implemented within schools. For the six-month follow-up survey, planned for Fall 2024, administered outside of school, a $50 electronic Visa or gift card will be provided. A number of steps will be taken to maximize participation and retention rates. The fact that the intervention and assessments proposed in this application will be endorsed by the Cherokee Nation and school leadership at the participating high schools will help maximize participation rates. Youth will receive reminders and compensation for their time. For youth who are missing from school during survey administrations, tactics to reach them for follow-up surveys may include emailing and texting to ask how they are, update social media, email, phone and other contact information, and reminding them about an upcoming survey. We will use procedures for tracking and follow-up surveys as we implemented in a long-term follow-up of a cohort of youth in Chicago, including secure internet and in-person survey administration options. Although some attrition is anticipated, a substantial proportion of the students recruited at baseline are expected to be retained in the study. In our previous prevention trial in the Cherokee Nation, we maintained over 80% participation across the three-year study.
Our recruitment and retention protocol requires careful planning and treating school leadership, parents and study participants with respect and courtesy. Our previous trials demonstrate this has worked well—we have consistently been able to recruit a substantial percentage of the sample and have experienced few refusals. As with all field studies, recruiting students and parents/guardians in this fashion necessarily introduces potential selection bias because those who participate may be systematically different from those who decline. However, maintaining a respectable baseline participation rate, conducting descriptive analyses to determine whether the final sample is representative of the school demographically and to ensure comparability on relevant characteristics between communities, and weighting to adjust for nonresponse helps offset the effects of selection bias. Also, bias will be somewhat further reduced by providing financial incentives and maintaining direct contact with schools, parents and students.

Measures
The Youth Experiences Survey is attached. It will be used to collect data from youth participants to assess substance use and related risks/harms, perceived availability of opioids and other drugs, knowledge and perceptions of consequences, values and beliefs about substance use, social normative beliefs around substance use, social skills and social support.

Each participant will be asked to complete a Contact Information Form during the final school-based survey in Spring 2024. The contact form will be a scannable paper form, separate from the tablet-based student survey, and students will be provided $5. The form asks about contact information to help us

maintain contact and reach participants for the follow-up survey. We will ask youth to provide phone numbers, email address, and home address. The Contact Information Form is attached. Mid-summer we will contact participants via text, call, or email to ask for confirmation of contact information. A $10 electronic Visa or gift card will be provided for confirming contact information.

III. Risk/Benefits

The data-gathering requirements and intervention activities of the proposed research pose no more than minimal risk to participants. The surveys will be designed to be of limited distress, although a student may be uncomfortable answering certain questions. The surveys are short—average completion time is expected to be 20-30 minutes. Participants will be reminded at the beginning of the survey that they are free to skip any questions or to stop the survey at any time. Our confidence in terms of the measures to be used is based on many years of experience in using these surveys. Moreover, students have reported a high level of comfort with the surveys and assessments in the past. Although rare, there is a possibility for the surveys to produce some stress or frustration, which will be carefully monitored. Thus, at most, participants may find these assessments boring, annoying, or frustrating.

There is potential for significant direct benefits of this project to participating adolescents and young adults; the evidence-based interventions are expected to improve several outcomes under study, such as preventing the onset and escalation of drug use and related risks/harms. The control sites will be offered the intervention materials at the end of the study, as well as the opportunity for teacher and staff trainings provided Cherokee Nation Behavioral Health during the active study phased (e.g., bullying prevention training).

The minimal risk of a breach of confidentiality, plus possible discomfort that may accompany some behavioral change efforts, is easily outweighed by the likely benefits.

IV. Data Security/Monitoring

Data collectors will be professional staff with training in Human Subjects Research. They will be thoroughly trained in the principles of the study and use of the survey methods. They will also be qualified to interact with adolescents, parents, and school administrators. Drs. Komro and Kominsky will coordinate and train on collection of survey data. An Evaluation Field Supervisor will oversee all field activities, including administration of assent forms, coordination with schools and teachers, and administration of assessments. The tracking and assessment databases will be linked by arbitrarily-assigned study numbers (not school ID or other such numbers) to ensure identifying information is not contained in the assessment databases. Data collected for the study will be transmitted immediately via cellular-connected tablets using REDCap or Qualtrics to the Emory University server where checks will be run for data consistency and quality. It is important to note that the schools will not obtain or maintain any individual-level survey results and research staff will not retain any identifying information; thus there will be no way to link names with survey results. Processes are in place to generate de-identified databases and statistical programs for analyses.

Prior to any member of the research staff initiating contact with research participants, they will be trained in the following areas: 1) Protecting human study volunteers in research in accordance with Emory and Cherokee Nation IRB requirements; 2) Understanding the project grant (background, application, and aims); 3) Demonstrated understanding of data collection forms; 4) Understanding how all forms are filed, both electronic and material (i.e. exact location, computer drive, folders, and which

electronic files need to be password protected); 5) Understanding which type of events need to be reported and the process of reporting (e.g., emotional reports related to incidence of victimization or violence, adverse events reporting, active suicidal/homicidal ideation, releasing information, etc); and 6) Survey and follow-up protocols. Training tasks will be organized by a checklist which will be completed during orientation. Prevention of minor adverse events will include the following. Participants will be acclimated to the study in the school, which will be familiar to them. They will be given time to relax and ask questions. They will also be assured that, if at any time they experience any emotional discomfort, they may request a break or ask to be discontinued from the study. The investigators have been conducting both clinical and research work with adolescents for many years. If a student reveals any abusive experiences, the interviewer will be required to report it to the school or a local authority. The PIs, in consultation with the IRBs, will determine if they are mandated to report the incident to an appropriate professional or authority.

Protections relevant to children.
We believe that study participation of adolescents and young adults, ages 15-20, involves no more than minimal risk. All of the interventions to be provided have been shown in experimental trials to benefit adolescents. Most have beneficial effects on drug use. Participation in surveys poses, at most, minor risks of discomfort.

Data Collection and Management Procedures.
We will collect data from youth to assess risk and protective factors, substance use and related harms. Age ranges of the youth will be from 15 to 20. Students will complete a short (20-30-minute) survey each semester within their homeroom, selected class period, or lunch period or on their own time through electronic survey distribution and once again approximately six months following graduation to monitor influences and outcomes. When in-school survey administration is not feasible students will be asked to participate in a private location through an electronic survey link. On average, each student will provide approximately seven data points throughout the project.

Data collectors will be professional staff with training in Human Subjects Research. They will be thoroughly trained in the principles of the study and use of the survey methods. They will also be qualified to interact with adolescents, parents, and school administrators. Drs. Komro and Kominsky will coordinate and train on collection of survey data. An Evaluation Field Supervisor, under the supervision of the PIs, will oversee all field activities, including administration of assent forms, coordination with schools and teachers, and administration of assessments. The tracking and assessment databases will be linked by arbitrarily-assigned study numbers (not school ID or other such numbers) to ensure identifying information is not contained in the assessment databases. Data collected for the study will be transmitted immediately via cellular-connected tablets using REDCap or Qualtrics to the Emory University server where checks will be run for data consistency and quality. It is important to note that the schools will not obtain or maintain any individual-level survey results and research staff will not retain any identifying information; thus there will be no way to link names with survey results. Processes are in place to generate de-identified databases and statistical programs for analyses.

The deidentified data collected within the CIAS CONNECT system will reside on secure servers at Michigan State University. Only the PI, the research project manager and the CONNECT coaches will have access to the link list of CONNECT ID to participant name.

Confidentiality

NIH's Certificate of Confidentiality (CoC) policy automatically issues a CoC for any NIH-funded projects using identifiable, sensitive information. Further information is included in the Confidentiality Certificate section.

V. Data Analysis

Throughout the study, age ranges of the students will be from 15 to 20. Students will complete a short (20-30-minute) survey each semester within their homeroom, selected class period, or lunch period or on their own time through electronic survey distribution and once again approximately six months following graduation to monitor influences and outcomes. When in-school survey administration is not feasible students will be asked to participate in a private location through an electronic survey link. On average, each student will provide approximately seven data points throughout the project, so we can analyze trends over time in the onset and escalation of risk and protective factors and drug use outcomes.

We will analyze the effects of the CMCA and CONNECT interventions on proximal outcomes (e.g., perceived availability of drugs, social normative beliefs, social support, self-efficacy, and normative estimates of peer drug use) and on distal outcomes of opioid and other drug use (e.g., prescription opioids without a doctor telling you to take them, marijuana use, alcohol use). The trial consists of "doubly repeated" measures--repeated measures nested within each student, plus students are nested within schools. Any statistical analysis that ignores lack of independence due to nesting will be subject to inflated type-1 errors. To account for both the clustering effect of students nested within schools and repeated measures nested within student, intervention effects on proximal and drug use outcomes will be estimated with generalized linear mixed models.

As part of our strategy to follow students into the first year after their expected graduation, we will employ extensive tracking procedures to maintain a high response rate across study waves. There may still exist students who miss survey administrations or who are lost to follow-up. As in our previous Cherokee Nation prevention trial, we will use multiple imputation to account for non-response over time and potential attrition. All available outcomes data will be used to impute missing outcome data from those with missing survey waves.

VI. Dissemination

Sharing of the data generated by this project is key to the project, especially if the intervention is successful. We anticipate that we will present on the intervention and evaluation process in the second year and at least annually on data collected after the second year when sufficient baseline data are collected. Sharing of the findings will involve a primary paper describing the study outcomes and papers that describes the study design and intervention implementation details, as well as submitting to lead workshops on the intervention approaches at relevant national meetings and conferences.

De-identified data for additional analyses will be available to outside individuals through contacting the PI and with approval of the Cherokee Nation Institutional Review Board. Access to data will not be possible until the publication and release of the main outcome papers. After this, we will institute a concept plan process where internal study staff first have the availability to write primary papers or give presentations on particular topics. If outside individuals then wish to analyze data, we will welcome this collaboration. Contact information for the PI will be listed on all manuscripts and publications as a means to access the data. We will abide by the Steering Committee's data and resource policy,

consistent with the relevant NIH policies, laws and regulations and with approval from the Cherokee Nation Institutional Review Board.

The current versions of the CMCA Handbook and CONNECT materials are available through the Emory Prevention Research Center's website (http://web1.sph.emory.edu/eprc/research/cmca-connect.html). We plan to update this website and the materials as we expand the interventions to address substance use.

Clinicaltrials.gov: We will ensure that clinical trial under the award are registered and results information is submitted to ClinicalTrials.gov as outlined in the policy and according to the specific timelines stated in the policy; informed consent documents for the clinical trial will include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov; and Emory University has an internal policy in place and of Office of Research Compliance to ensure that clinical trials registration and results reporting occur in compliance with policy requirements.

At the conclusion of this project, all parents and students will be sent a letter summarizing the aggregate results of the study. No personal identifying information will be provided, rather a summary of the overall study results will be provided so that families will be informed about study findings. Additionally, a lay summary with findings will be submitted as part of the study closure with the Cherokee Nation IRB. Finally, as with the previous alcohol prevention trial every effort will be made to make presentations within the Cherokee Nation organizational structure and to the school administrations to help ensure that the results are adequately disseminated to the communities themselves in addition to scientific publications and presentations to broader scientific and prevention communities.

Bibliography

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Esbensen, F.A., et al., Differential attrition rates and active parental consent. Evaluation Review, 1999. 23(3): p. 316-335.

Gottfredson, G.D., E.M. Jones, and T.W. Gore, An assessment of a program to prevent problem behavior by development school capacity for guardianship. 1996, Ellicott City, MD: Gottfredson Associates, Inc

Pokorny, S.B., et al., Do participation rates change when active consent procedures replace passive consent. Evaluation Review, 2001. 25(5): p. 567-580.

Informed Consent
A series of mailings (1 introduction postcard, 1 informed consent letter, 1 reminder postcard) will be sent to parents/guardians of all 10th grade students in the participating schools. The letter sent to parents includes the information required for informed consent set forth in 45 CFR 46.116. Parents can refuse participation for their child by calling Dr. Kominsky (contact information provided) using a toll-free number or by mailing a pre-addressed postage-paid postcard. Students will provide assent to participate. Assent forms will be read aloud prior to the administration of each survey. Follow-up calls or in-person meetings will be made to parents who request more information or are otherwise unreachable. The consent and assent forms include a statement indicating that they may decline participation without any repercussions and may terminate participation in the surveys at any time. The form also states that participation in this study will in no way influence their school standing, grades, or evaluations, and for parents, that it will not affect their status in the school, with the Cherokee Nation, or any other standings. Methods to ensure confidentiality will also be explained. Any questions youth have will be answered. Only those who have been read assent forms and whose parents have not refused consent via the postcard or phone will be included in the study. Copies of the consent mailings and assent form are included in this submission.

Waiver of Written Parental Consent
In our previous prevention trial in the Cherokee Nation, which included the community (CMCA) and screening and brief intervention (CONNECT) prevention interventions and a youth survey as proposed here, we were granted a waiver of written parental consent. We understand in order to justify a waiver of written parental consent; the following four criteria must be met [45 CFR 46.116 (d)]:
1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
We believe our procedures and study protocol fulfill these four criteria and the criteria outline in 45 CFR 46.408. This has been confirmed by continued prior approval of these procedures by the University of Florida Institutional Review Board and Cherokee Nation Institutional Review Board in 2011 and Emory University's Institutional Review Board in 2015. Our justification to waive the requirement of written parental consent is as follows:

(1) The research involves no more than minimal risk to the subjects.
Risks posed by the survey are no more than minimal. The questions have been used with thousands of children since 1975, and are the same as those used in federal government surveys, such as those supported by CDC and NIDA. The survey does not probe psychologically (such as with the use of clinical psychological tools), nor does it ask questions about physical and sexual abuse. Youth, ages 15-20, are not coerced into completing the survey. They are clearly told that they do not have to complete the survey if they do not want to and that they can skip any and all question(s) that they want to. To further protect the confidentiality of the subjects, NIH's Certificate of Confidentiality (CoC) policy automatically issues a CoC for any NIH-funded projects using identifiable, sensitive information. We inform youth that their answers will remain confidential and that the Certificate of Confidentiality protects them. Responses are kept completely confidential. Study IDs are assigned to the surveys and identifying information is kept in separate, secure encrypted electronic files at Emory University. No one has access to any of those files except for trained study personnel. Only the PI and research coordinator has access to the link list of study ID to participant name.

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects.

The letter sent to parents includes the information required for informed consent set forth in 45 CFR 46.116. The information that will be sent to parents explains the research purposes and duration; describes the procedures to be followed; lays out reasonable foreseeable risks; describes the extent to which confidential data identifying the subject will be maintained; explains whom to contact for answers to questions about the research; states that participation is voluntary and can be discontinued at any time; and indicates that refusal involves no penalty or loss of benefits. The parents can refuse participation for their child by calling Dr. Kominsky at Cherokee Nation Behavioral Health a toll-free number or by sending in a pre-addressed, stamped postcard. In addition, youth are given an assent form.

Youth participants also have the opportunity to easily refuse participation at any point in the survey process, including being able to skip any questions they choose. Hence these procedures meet national ethical and legal standards set forth in 45 CFR 46. The protocol has been carefully reviewed and approved by the IRB at the University of Florida and Cherokee Nation for the previous trial in the Cherokee Nation and is based on the protocol followed in our previous research over the past 25 years.

(3) The research could not practicably be carried out without the waiver or alteration.
A requirement to obtain written parental consent will significantly undermine the validity of the research study due to very low parental response rates among students most at risk for substance use, our key dependent variable (Dent et al., 1993; Ellickson & Hawes, 1989; Esbensen et al., 1999). In general, studies comparing various parental consent procedures suggest that requiring written consent can lead to biases on significant dependent variables that may adversely affect the generalizability of results of studies of adolescent drug use (Esbensen et al., 1999; Pokorny et al., 2001). It has been shown that requiring written parental consent threatens the scientific validity of research since only 28% to 43% of parents take the time to return signed consent forms, yet only about 3% of those actually withhold consent (Gottredson, Jones & Gore, 1996). When requiring written consent, Ellickson and Hawes concluded that nonresponse was considerably more likely to signify latent consent than a deliberate refusal. In addition, researchers who have used active consent have reported unacceptably low response rates and underrepresentation of important groups, including racial/ethnic minority youth (Dent et al., 1993; Ellickson & Hawes, 1989; Esbensen et al., 1999). Therefore, if written parental consent was required in the proposed study, we would only be surveying less than half of the students who participated in the prevention program, with obvious bias in who completes the survey. In a study comparing parent consent procedures, Ellickson and Hawes concluded that carefully designed procedures that do not require signatures from parents can inform parents while avoiding the large nonresponse rates and sample bias associated with requiring written consent. We will send a series of personal letters (postcard, consent letter, postcard reminder) to each parent.

(4) Whenever appropriate, subjects will be provided with additional pertinent information after participation.
At the conclusion of this project, all parents and students will be sent a letter summarizing the aggregate results of the study. No personal identifying information will be provided, rather a summary of the overall study results will be provided so that families will be informed about study findings. An example of the study findings brochure from our previous study is included in this packet.

In summary, the risks posed by the prevention programs and survey are no more than minimal. Youth, their families, schools and communities have been exposed to these alcohol/drug prevention strategies that have been previously tested and found to reduce alcohol and other drug use among young people. Every effort is being made to reduce risk and protect the confidentiality of the subjects. A waiver of the

requirement for written parental consent is critical to avoid sample selection bias. The knowledge gained from this research relies on inclusion of a nonbiased sample of subjects.

Consent Mailings- Postcards

Dear Parent/Guardian(s):

You will be receiving an important letter regarding your high school student's participation in a survey at school within the next week. This survey is part of a project in which Emory University and Cherokee Nation Behavioral Health will be working with your son or daughter's high school. Please be on the look out for this important information!

The letter will explain the project in detail but if you have any questions please contact Dr. Terrence Kominsky at 1-800-256-0671 ext. 4984 or at his direct line at 918-207-4984.

Thank you!

ROLLINS SCHOOL OF PUBLIC HEALTH

Dear Parent/Guardian(s):

This is a reminder concerning the letter you recently received about your high school student participating in a survey at school. Please return the postcard included with that letter if you DO NOT want your son or daughter to participate.

If you have any questions or concerns please contact Dr. Terrence Kominsky at 1-800-256-0671 ext. 4984 or at his direct line at 918-207-4984.

Thank you!

ROLLINS SCHOOL OF PUBLIC HEALTH

Consent Postcard Text

Return this card **ONLY** if you **DO NOT** want your child to participate in the Emory University and the Cherokee Nation Behavioral Health's Youth Experiences Survey.

Please fill out the following information:

Child's name (please print) _____

Address_____

City_____ State _____ Zip Code_____

Parent's/Guardian's name (please print)_____

If you have questions or concerns, contact Dr. Terrence Kominsky, free of charge, at 1-800-256-0671 extension 4984 or at his direct line at 918-207-4984. Thank you!

Confidentiality Certificate

NIH's Certificate of Confidentiality (CoC) policy automatically issues a CoC for any NIH-funded projects using identifiable, sensitive information which includes this study. We inform youth that their answers will remain confidential and that the Certificate of Confidentiality protects them. Responses are kept completely confidential. Study IDs are assigned to the surveys and identifying information is kept in separate, secure encrypted electronic files at Emory University. No one has access to any of those files except for trained study personnel. Only the PI and research coordinator has access to the link list of study ID to participant name.

Contact Information Form

We are excited to keep in touch with you and see how you are doing in about six months. We would like to send you a brief survey and you will be paid $50. Are you willing to provide us with information that will help us contact you? We will keep this information separate from your survey answers and completely confidential.

We need the following information because it will help us contact you for a brief paid survey in the fall. Remember, we will keep this information separate from your survey answers and completely private. We will not share this information with anyone.

OK to text you about the paid survey?

What is your cell phone number?

What is your home number?

What is your personal email (not your school email)?

What is your current address?
Address:
City:
State:
Zip code:

THANK YOU!