Family Listening Program: Multi-Tribal Implementation and Evaluation:

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1) HRPO Protocol Title (Version #1 and/or Version Date: 9.19.2014) IRB#14-289

Family Listening Program (FLP): A Multi- Tribal Implementation and Evaluation (National Institute of Drug Abuse Grant #1R01DA0371740 01)

2) IRB Review History

We are seeking approval of this protocol which is a result of a successful Community Based Participatory Research (CBPR) partnership with Jemez Pueblo, Ramah Navajo, and Mescalero Apache in the piloting of the Family Listening/Circle Program (FL/CP) through two different studies funded by the Native American Research Center for Health (NARCH III 2005-2009 & IV 2009-2014). This new protocol submission is required due to new NIDA funding (1R01DA037174-01, 2014-2019) with an expanded more rigorous research study with the three tribal communities: Jemez Pueblo, Ramah Navajo, and Mescalero Apache. With the initial piloted studies completed FL/CP established working Tribal Research Teams (TRTs) from the Pueblo of Jemez, Ramah Navajo, and Mescalero Apache which are still intact and in place for full program implementation and effectiveness testing through a longitudinal quasi- experimental design involving a long-term, multi-tribal/academic research partnership. Under this five- year R01 effectiveness trial, tribal partners are committed to assessing the program's effectiveness and disseminating the approach and intervention within Indian Country as a best practice in reducing substance abuse health disparities, with TRTs collaborating on all research activities implementation, interpretation/ analysis, and dissemination plans.

The feasibility and piloting trials (first in the Pueblo of Jemez and Ramah Navajo, under HRRC #6-113; and then in the Mescalero Apache Nation, HRRC #11-217 & SWT-2011-005), produced the program design and curricula for each tribe; and the common recruitment design for participants, consent forms, measurement tools for parents and children, and data collection procedures which will all be used in the new effectiveness trial. More specifically, the feasibility trial with Mescalero Apache enabled us to refine our protocols from previous HRRC#6-113, such as the measurement tools (reducing number of questions and taking out unnecessary and more invasive questions).

3) Objectives

The purpose of the research project is to utilize a participatory research approach in partnership with three communities to test the effectiveness of an existing intergenerational culturally adapted curriculum. With Native American Research Centers for Health (NARCH) funding, the FL/CP was co-created and pilot tested by CBPR partnerships between the University of New Mexico Center for Participatory Research (UNM-CPR) and three tribal communities, the Pueblo of Jemez, Ramah Navajo and Mescalero Apache. These existing long-term partnerships have co-produced the tribal-specific FL/CP curriculums in Pueblo, Navajo and Apache versions. This CBPR project supports the rigorous testing of the intergenerational Family Listening/ Circle Program as a culturally centered and evidence based prevention program that has produced promising

preliminary data in reducing substance abuse risk factors for elementary school children. This grant will not only aggregate sufficient numbers to test FL/CP effectiveness but also illustrate how an intervention can disseminate and share "evidence- based processes and components" and also integrate understandings from implementation and CBPR science, that culture and community context must be integrated for the intervention to be effective and to generate community ownership. The R01 specific aims over a five year period are as follows:

Aim One:

Rigorously test the effectiveness of the Family Listening/Circle Program (FL/CP), with a comparative longitudinal design within and across three small tribal communities, with 4th graders to prevent substance abuse initiation disparities and to strengthen family well-being. Through a quasi- experimental longitudinal design, we will test effectiveness of the FL/CP prevention program with an intervention group of 4th graders as compared with other 4th graders, both within and across the three tribes. Quantitative pre-, post-, 6- month and 1 year –post measures of substance abuse risk and protective factors will be triangulated with qualitative data, also comparing children and parent responses on psycho- social factors, family communication and cultural connectedness. Process evaluation will assess satisfaction, quality, and fidelity to both core evidence and specific cultural curriculum components.

Aim Two:

Through CBPR, to support the three Tribal Research Teams (TRTs) to transform their research capacities into local prevention research infrastructures and a shared partnership. Building from the strengths of UNM-CPR's partnership with Jemez to help coordinate the 3 tribes in the trial, each TRT will receive trainings in advanced CBPR and prevention science, with annual collaborative face-to-face TRT meetings to share lessons learned and support local tribal structures for future prevention research and programs. A novel CBPR conceptual model will guide evaluation of UNM-CPR and TRT partnership processes to assess effectiveness in fulfilling grant objectives and in reducing substance abuse.

Aim Three:

Assess additional program effects on other health, education and youth programs and leaderships within the three tribes. The FL/CP has potential for deep cultural embeddedness and community integration into other health and education prevention programs. We plan to assess knowledge about FL/CP and effects on tribal programs and leadership by interviewing people with varying degrees of closeness. Through interviews with program managers, staff educators, and tribal leaders, we will assess implementation and diffusion outcomes, such as potential for sustainability, pathways of information exchange, level of integration of curriculum into other programs, and multi- program collaboration.

In sum, the tribes and the University of New Mexico Center for Participatory Research are building on committed CBPR partnerships to test the effectiveness of our innovative culturally-centered evidence-based and empowerment intervention with its integrated theoretical model. This grant provides an opportunity to reduce substance abuse in three tribes, to strengthen research capacity among tribal partners for future prevention research and programs, and to make a difference in substance abuse prevention research

designs nationally, showcasing how CBPR can integrate evidence-based interventions with cultural-specific contexts. Our FL/CP intervention, consisting of a CBPR process, that reintegrates culture into an evidence- based core, will then be available as a key model for other tribes across the nation.

4) Background

The three pilots co-created the tribal specific curricula (using the background rationale crossed out above) incorporating both evidence-based family strengthening approaches and cultural and community knowledge and evidence to embed the program within each specific tribal community. The three pilots also established committed partnerships through the feasibility trials who now have the capacity to co-implement and co-lead the effectiveness trial.

SIGNIFICANCE for RO1: The epidemiology of American Indian (AI) substance abuse disparities has been well-documented (Beauvais, 1980; Beauvais, 1992; Beauvais, 1996; Mail and Johnson 1993; Okwumabua and Duryea 1987; Swaim, 1989) with Als suffering disproportionately from alcohol, illegal substance use, and suicide when compared to other races [NMDOH, 2007; Szlemko, Wood and Thurman, 2006]. Nationwide surveys have found that both current drinking and heavy drinking are most prevalent among Als (Miller, 1996). Alcohol and illegal substance use have been strongly associated with suicide attempts by AIs nationwide (Borowsky, 1999). From the US 2010 Census, the AI population of New Mexico (NM) was 10.1% of the total compared with 1.2% nationally. Proportionally, about 43% of this population was under 25 years of age (United States Census, 2010). According to the 2012 New Mexico's Racial & Ethnic Health Disparities Report Card, American Indians had the highest alcohol-related mortality rate of 97.3/100,000, compared to 50.8 deaths per 100,000 for all New Mexicans (NMDOH, 2012). In 2011, the NM Youth Risk & Resiliency Survey reported that for AI children grade 6th- 8th binge drinking rate 6.4%, and rate of children drinking before the age of 11 as 12.3%. In the same year for AI youth grades 9-12, respective rates for each NMYRRS category was 38.6% ever drank, 24.7% current drinking, and 28.4% reporting they drank before the age of 13 (NM Youth Risk and Resiliency Survey, 2009). These youth are linked to alcohol/drug abusing peer clusters, and poor family and peer group associations (Oetting, 1989). Youth suicide rates for NM (all races) is more than double the national rate, with AI suicide rate nearly 4 times the national rate (NMDOH, 2012), and the attempted suicide among NM AI youth was 10.5%. For NM AI children (grades 6-8) the rate of suicide ideation was 24.6%, compared with 19.8% for all other NM children (NM Youth Risk and Resiliency Survey, 2009). Early substance use onset shows AI children begin using alcohol and other drugs earlier than any other ethnic group (Beauvais, 1996) due to multiple factors, including ineffective parenting strongly associated with parental substance abuse (Conger, 1997; Conger, 1991; Loeber, 1998), conduct disorder transmitted across generations (Gottesman and Goldsmith, 1994; Lahey, 1988; O' Connor, 1998; Silvery, 1996), and ineffective family sanctions, partly associated with the historical trauma of boarding schools which removed many of the current parents from their protective community and cultural norms (Duran, Duran and Braveheart, 1998; Duran and Duran, 1995). Peer pressure (Conger, 1997; Conger, 1991; Duncan, 1995; Dinges and Oetting, 1993) and early onset are also critical risk factors and predictors for

AI youth alcohol use or progression to other substances (Hawkins, Cummins and Marlatt, 2004; Kandel, Yamaguchi and Chem, 1992).

Child Protective Factors and Theoretical Approach: Despite the risks, universal primary prevention programs have been shown to be effective at deterring AI experimentation with alcohol and drugs if they occur prior to initial substance use (Hawkins, Cummins and Marlatt, 2004). Work with 4th graders who are on the brink of early adolescence, with its challenges of role confusion and identity crises, provides an optimal time for influencing a key turning point so that these youth experience success in personal relationships or task accomplishment that may change their lives to a more adaptive trajectory (Rutter, 1987). According to the 2011 NM YRSS, "Students with close relationships with their parents, teachers, peers, and adults in the community were less likely to engage in risk behaviors. Students who said it was 'very much true' that they had a parent or guardian in the home who 'talks with me about my problems' were less likely than other students to smoke cigarettes (13.0% vs. 23.0%), use cocaine (2.4% vs. 6.4%), binge drink (16.5% vs. 25.0%), or attempt suicide (4.7% vs. 10.4%)" (NMYRRS, 2009). FL/CP adopts this positive youth development model following successful programs, which "strengthen social, emotional, behavioral, cognitive, and moral competencies; increase healthy bonding with adults and peers; and combine the resources of the family, the community, and the school" (Catalano et al, 2004). To support positive youth development, family-strengthening approaches (Kumpfer, Molgaard, & Spoth, 1996; Brody et al, 2012; Whitbeck et al, 2001) are based on social cognitive theory, building self-efficacy and skills in parent and child communication (Bandura, 1977); problem-coping strategies which help children avoid psychological distress (Dumont and Provost, 1999); as well as greater bonding with and reliance on parents.

Whitbeck et al. (2002), identified enculturation (or cultural connectedness, measured by participation in traditional activities, cultural identification, and spirituality) as another protective factor and buffer against the negative impact of discrimination for AI adults; and particularly for children, aged fifth to eighth grade to impact academic success (Whitbeck, 2001). Enculturation was also found to have indirect effects on depressive symptoms, suicidal ideation; and self-esteem, supporting growing research that cultural values and practices serve as protective factors for AI children (Coggins, Williams, & Radin,1997), with strong cultural identification as one of the most important for increasing self-efficacy, school performance and abstinence from drugs and alcohol (Whitbeck et al, 2001). Core Indigenous theory in education also showcases how culture, language, and community are central to learning (Pankratz et al, 2006; Cajete, 1994). Cultural indigenous theory is particularly important for alcohol abuse in that AI age-specific expectations and sanctions against deviant behavior have been weakened due to discrimination and disruption of cross- generational traditional teachings (Duran, Duran, & Braveheart, 1998; Duncan et al, 1995); and that mainstream individualistic refusal skills, found in some evidence-based approaches, may conflict with tribal values of belonging to the collective. Finally, empowerment theory also bolsters collective protective factors, with youth who increase their self-efficacy to work with each other and participate in community action showing improved mental health and educational outcomes (Wallerstein, 2006; Altman & Feighery, 2004; Holden et al, 2004; Berg, Coman, & Schensul, 2009). The central method of empowerment comes from Brazilian

educator Paulo Freire (1970) who promoted learning through listening, dialogue, and community actions (Lipari, 2010; Wallerstein & Auerbach, 2004), processes consonant with cultural tribal norms of listening, respectful dialogue, and collective responsibility.

5) Inclusion and Exclusion Criteria

Inclusion criteria includes any families from Mescalero Apache, Jemez Pueblo and Ramah Navajo with a fourth, grade aged child and their parents or guardian, and grandparents who will volunteer to participate.

Those whom are ineligible in this study are: those that do not give consent and/or assent to participate; those that do not identify as tribal members of Mescalero Apache, Jemez Pueblo and Ramah Navajo or as the family member of someone that identifies as Mescalero Apache, Jemez Pueblo and Ramah Navajo; children and that are not in the targeted range of fourth grade. The inclusion for the comparison group follows the same criteria, in having a child from the fourth grade and being tribal members, but who decide not to participate in the FL/CP program and are willing to assent/consent to take the pre and post-tests.

6) Number of Subjects (Recruitment Target)

Target number of participants is 12 child participants and at least one parent/guardian in the family for a total of two members from one family, an expected 12 families annually for an overall total of 48 family participants over four years per community. Because of expected drop of 1-3 families (known attrition from our feasibility trials) by end of the twelfth session, we will initially recruit 13-14. Comparison participant numbers will be 12 children and 12 parent/or guardians.

The expected sample size for the families will total 576 participants from Fiscal Years 1, 2, 3, and 4 only (3 data collection waves total). Each wave per year will recruit 12 Program and 12 Comparison families. Based on our multiple pilots with each tribe, we have determined a Family will be represented by at least 1 parent with 1 child; thus our participant totals (program & comparison) are 24 youth and 24 parents per tribe per year (48 participants X 3 tribes X 4 years (data collection waves) = 576). Furthermore, based on previous pilots with each tribe it is anticipated the sample will enroll more females than males at an approximate ratio of 70:30 and the majority of participating parents to be female.

Table 2.	**FY01 (2014-2015)**		**FY02 (2015-2016)**		**FY03 (2016-2017)**		**FY04 (2017-2018)**		**FY05 (2018-2019)**	
Data Collection	Sep 14'	Mar 15'	Sep 14'	Mar 15'	Sep 14'	Mar 15'	Sep 14'	Mar 15'	Sep 14'	Mar 15'
***Wave 1**	Pre-Test	Post-Test		1-Yr Follow up						
***Wave2**			Pre-Test	Post-Test		1-Yr Follow up				
***Wave3**					Pre-Test	Post-Test		1-Yr Follow up		
***Wave4**							Pre-Test	Post-Test		1-Yr Follow up
* Each data collection wave (4 Waves totaling 288 families) includes three data collection points (pre, post,and 1 Yr Follow Up) for intervention & comparison families.										
WAVE TOTAL	= 12 Program Families (12 families X 3 tribes X 4 waves = 144 families (144 students + 144 parents = 288 participants)									

= 12 Comparison Families (12 families X 3 tribes X 4 waves = 144 families (144 students + 144 parents = 288 participants)

7) Recruitment Methods

Members of the tribal research team will work with the schools from each community and will identify the potential participants from the fourth, grades of these schools. Letters will be sent home with the fourth grade children and TRT members; and by TRT members presenting to the children in their classrooms on the Family Listening Program and how interested students may participate in this research project. The attached recruitment letter will have minor changes by TRT members who will insert their contact information specific to each community. (see Attachment A). Should a child express an interest then the research team member will follow-up with the parents of the child and the compenents of the Family Listening/Circle Program will also be shared.

Based on previous pilots with all tribes, all youth participants will be between 9-10 years of age and be enrolled in 4th grade. Evidence of community support and the ability to recruit participants, implement measurement and protocols, and oversight exists through the previous feasibility trials and earlier grants and collaborative work. . At a minimum, Mescalero has 5 years, Ramah has 11 years and Jemez has 14 years of NIH research funded experience with the UNM Center for Participatory Research; which resulted with this multi-tribal application to test effectiveness. The current partnering opportunity stems largely from feasibility and development efforts, multiple pilot projects, presentations and publications. The Tribal Research Teams (TRTs) themselves, are also direct outcomes of previous Community-Based Participatory Research (CBPR) projects that have elevated Advisory Councils (typical of most CBPR projects) to more action-oriented shared leadership bodies that co-design, co-implement and co- translate findings while providing direct research oversight through tribally-driven research and approval processes, and a multi-tribal/academic partnership connected together by UNM-CPR.

Child and parent participants and child non-participants. Beginning in YR01 the TRT will begin recruitment, in a manner consonant with the feasibility trials. The TRTs will make informal presentations in 4th grade classrooms and will send home letters of invitation to participate. Letters will be given to all 4th grade students to take home for their parents review. The invitation letter will provide an overview of the FL/CP and invite interested parents and children to learn more. TRT and UNM team members will follow-up with interested parents individually. During the individual information session, potential participants will be told what FL/CP is and involves the primary language of the community (Towa, Apache and Dine languages respectively), or bilingually, with English depending on the preference of the potential participants. After learning about the intervention program, TRT researchers will determine whether the family is willing to participate. Research team members will be prepared to provide informed consent and answer any questions. However, potential participants will be encouraged to take time to weigh the costs and benefits of the program; they can take time to think about it and contact the research team member at a later date. If at a later date they decide to

participate, research team members will arrange a time to meet and perform the informed consent process. FL/CP participant families will be enrolled on a first come first serve basis. The self-selected 4th graders and parents who choose to participate will be drawn from a pool of candidates from several points of risk: the socioeconomic status of the students' families is relatively low, living in areas of poverty, living in rural communities and the majority of students live in single parent households. Those not selected to participate or who decline to participate will be invited to take part in the research study verbally by TRT members (to take pre and 2 post-tests) as non-program participants serving as comparisons. The described recruitment process is the preferred method by the TRTs to date; because it ensures a) involvement with this study is entirely participatory and voluntary and b) an understanding of the research involved by potential participants is obtained and discussed to satisfaction of TRT members, with UNM research team members available as necessary.

Leaders, managers, educators, and/or staff. For the third aim of the grant, in the first program year, the UNM and community TRTs will conduct a review of community organizations and prevention and youth programs in the community and at schools. From this review of programs, the pool of managers and educators will be identified. Community/traditional leaders may not be affiliated with programs therefore we will rely on the community knowledge and connections of the Tribal Research team members to recruit these leaders. Starting in year 1 and continuing through year 5, TRT members will recruit those identified by phone or face-to-face communication. The consent process as detailed above will occur immediately prior to the individual interview. Potential participants will be contacted and interviews will be conducted during the fourth quarter of each program year. The described recruitment process is the preferred method by the respective TRTs because it ensures a) involvement with this study is entirely participatory and voluntary and b) an understanding of the research involved by potential participants is obtained and discussed to satisfaction of TRT members, with UNM research team members present and available as necessary.

8) Study Timelines

Attached updated study timeline (see Attachment B)

9) Study Endpoints

Our final endpoint will be the collection in year 5 of the one-year post-test of the final program implementation groups in year 4. A potential reason to terminate the study would be when there are no voluntary family participants.

10) Research Setting

Describe the sites or locations where your research team will conduct the research.

The Family Listening/ Circle Program will be conducted in three tribal communities in New Mexico. The program is a dinner program with four facilitators and 12 families (child/parent/invited elders) held in tribal facilities, such as a school, a library, an

intergenerational center, and there is no other business taking place at that time. The UNM Center for Participatory Research (UNM-CPR) has invested in several CBPR tribal partnerships to create a bidirectional environment open to partnered research and to prevention programming that can be tested systematically to improve children, youth, and family wellness. Each partnership has been developed with UNM's commitment of regular (at least monthly) visits to each community, despite the rural distances; from Albuquerque, Jemez is one hour north, Ramah Navajo is 2.5hours west, and Mescalero is 3 hours south. Described below is a brief overview of each tribe and history of each FL/CP partnered development.

Jemez: The Pueblo of Jemez, with 3400 people, as the only Towa-speaking people, places language fluency at 80-85% [POJ, 2013], with the Hemish people practicing a high degree of traditional and cultural knowledge. The preservation of Towa and the Hemish ways of life remain a tribal priority in all facets of life, not only for the sake of cultural preservation, but also because health and educational attainment of tribal members is believed to be affected by loss of language and culture. Like many other AI communities, the Pueblo of Jemez faces challenges of high rates of alcohol use, substance abuse, and suicide. According to the 2009 Youth Risk Behavior Survey for Jemez, aggregating 9th-12th grades, 46.8% had drank alcohol in the past 30 days, with 15.2% attempting suicide (Tribal unpublished data), in comparison to the national rate of 7.8% [NMYRRS, 2009]. The partnership between UNM-CPR and the Pueblo of Jemez started in 1999 with 4-years of CDC funding to identify Pueblo cultural strengths, social capital, and community capacities. Focus groups and individual interviews with >60 tribal members, including youth, identified the importance of cultural transmission of Hemish traditions and language, also coupled with concerns about intergenerational family breakdown and substance abuse; and a desire from elders and youth to engage with each other, but who also faced problems with communication [Wallerstein et al., 2003]. With these findings, the Jemez Advisory Council requested help to develop a culturally-based family prevention intervention to start with younger-age children; and NARCH III (2005-2009 HRRC #06-113) was born, to co-develop a family program, with Ramah Navajo community as a second tribe. Jemez co-developed its version, conducted 2 pilots and inserted elements into a summer youth program. Currently, UNM-CPR and Jemez (HRRC # 11-055) are also pilot- testing an intervention for high-risk high school youth, RezRIDERS, funded by NIDA, 2012-2015.

Ramah Navajo. Tribal rolls estimate that there currently are 3,500 people in the Ramah Navajo community, with over 400 students in Pine Hills Schools, Head Start through 12th grade, served by a full-time staff of 85. In terms of alcohol use, the 2003 Navajo Nation Middle and High School Youth Risk Behavior Survey (Tribal unpublished data) found that 40% of middle school students and 69% of high school students had more than one drink of alcohol in their lifetime; with 22% of middle school children using alcohol in the past 30 days. Furthermore, 36% of Navajo Nation middle school students and 67% of high school students had used marijuana during their lifetime (with 25% of middle schools students and 38% of high school students using it in the past 30 days), compared to U.S. rates for high school students of 42% lifetime and 24% for the past 30 days. The Ramah Navajo UNM-CPR partnership began in 2000 with CDC REACH funding to

develop community capacity to increase cervical and breast cancer screening. The Ramah Advisory Council requested help in creating a comprehensive community profile that would assess capacities as well as historic losses and a range of health, education, housing, and other community issues; and NARCH I funding was obtained [English, et al. 2004; Cashman, et al., 2008]. Cultural capacity items, which included elder and youth questions developed from the Jemez qualitative work [Oetzel, et al, 2011], were incorporated into the Ramah profile and led to a similar analysis: that cultural preservation was highly valued, but there were concerns for loss and family communication breakdown. The Advisory Council, similar to Jemez, requested help to develop a culturally based family intervention and joined in the NARCH III application to co-develop and contextualize the program within Navajo culture and language. One pilot test was conducted of the Ramah Navajo version of 10 families.

Mescalero Apache: The Mescalero Apache Community with 4000 enrolled members is located in south central New Mexico; about 100 miles from the Texas border and is three hours south of Albuquerque. There are three sub-bands, Mescalero Apache, Chiricahua Apache, and Lipan Apache, which comprise the tribe. Approximately one-half of the population is under the age of eighteen. Though Mescalero has a variety of well-established alcohol and medical treatment programs, which serve tribal members and others, the FL/CP was the first prevention program in Mescalero schools which is culturally centered and targets youth at the vulnerable age before the majority of experimentation begins. Under the Core of Albuquerque Area Indian Health Board's NARCH III, a community member from Mescalero Apache participated as an advisory member to the Scientific Community Advisory Committee since 2004; and had the opportunity to hear regular reports about the process and progress of the NARCH III FL/CP with Jemez and Ramah Navajo. As a result of hearing about the NARCH III Program, Mescalero requested to co-write NARCH V with UNM- CPR to co-develop an Apache version and implement the FL/CP within their community. With NARCH V, 2009-2013 funding cycle, we adapted the FL/CP curriculum to Mescalero Apache cultural values and ways of life and conducted 2 pilot sessions with families.

11) Study Methods

Provide a step-by-step description of all research procedures in chronological order.

a) The tribal research teams will recruit initially 13-14 families (knowing a couple families may drop based on pilot experience) to have 12 families from each tribe with fourth grade school children to be program participants. Families to include a child, parents, and elder family member. TRT members will recruit child participants and their parents and elders through invitation letters and through working with teachers to present in classrooms at each tribe's local elementary schools that serve tribal children. In addition, 12 families will be recruited to be comparison families.
b) Tribal facilitators, who are already trained, will train new facilitators (to expand the capacity within each community) in curriculum presentation/administration and process evaluations.

c) Tribal research team members, who are already trained, will administer pre/post and one-year post surveys with parent and child participants, and with comparison parents and children. UNM research team will provide support. We have chosen not to include elders in the quantitative instruments, as their primary (and sometimes only) language is the tribal language; elders do participate in mid-program and end of program discussions on program satisfaction and how program can continue to meet family needs. The post-tests include two open- ended "360" questions: asking parents how their child and family have changed, and asking children, how their parent and family have changed. For this RO1, we have adopted the use of laptops for data input, at the request of the IRB to provide greater guarantee of confidentiality for the children and parents.

d) Tribal facilitators will administer the twelve two to 2 1/2 hour sessions of the prevention/intervention family program UNM research team will provide support. Each of the tribes has trained facilitators (who are teachers, educators, behavioral health counselors, and prevention and cultural/language staff), with four needed for each FL/CP program implementation, two working with the adults and two working with the children during their breakout groups, and working together when the families are sharing what they learned. Each year, at least two trained facilitators will participate (overseeing the facilitation) and the TRTs will recruit and train others in subsequent years to expand the pool of tribal members knowledgeable about the program overtime. During the previous pilot funding, the UNM team provided training and support during the sessions. In this RO1, the tribal facilitators are trained and will be leading the curriculum. UNM team members will join periodically to provide support and to observe. Two of the facilitators in each group have taken the CITI training because they are also involved in data collection. All have been trained in confidentiality issues, motivational interviewing, facilitation of groups, and know the behavioral back-up protocols to refer children or parents if needed. (DSMP attached).

e) The intervention curriculum follows the exact curriculum developed in the three tribal communities during the pilot funding. Based on the pilot experience, the curriculum has been formalized into a systematic common format, with twelve weekly sessions, held at dinnertime for 2 and 2 1/2 hours. The program is held in tribal facilities, such as a school, a library, an intergenerational center, and there is no other business taking place at that time. Occasionally a session is postponed to the next week due to tribal community events. The twelve session themes are:

Welcoming
Tribal History (Part I)
Tribal History (Part II)
My Family
Tribal Way of Life
Community Vision
Community Challenges
Communication, Help Seeking & Problem Solving
Recognizing Types Of Anger & Managing Anger
Being Different & Positive Relationships
Building Social Support
Making A Commitment & Community Project Presentations

Each session starts with a collective dinner with families eating together (as a prevention strategy in itself), they then practice their Indian and clan names. The sessions are led by facilitators in their own language or bilingually, as interactive activities. The facilitators then divide the families into children and adult groups into separate rooms to address the theme of the session (with two facilitators per each group), and they then return together at the end of the session to share their learnings. For example in the Visioning session, the adults create their pictorial visions using crayons and markers, the children create their visions, and then they get back together as a whole group of 12 families to share their visions from different generational perspectives. All the children are given a chance to share first, with some parents and elders sharing after. The sessions always end with the children and adults writing in their journals which are individual pages that they then put in their curriculum binders. Families are then given their "home practice," which is a task that the families do together during the intervening week. The facilitators collect the curriculum binders after each session to bring back to the families the next week.

f) Process data will be collected during program implementation. Our well-tested process instruments include: journals by children and parents as the last activity of each session, facilitator logs as to activities completed and quality of interaction observed, and discussion groups at mid-point and at the end of the Program.
g) In YR01, for the third research aim of the grant, each TRT will collaboratively identify key individuals within each tribal setting, where program diffusion will be most evident, i.e. those with the strongest program links to FL/CP, such as educators who teach next to teachers who are facilitators in the Program, or other Program leaders who work with youth. From YR01 though YR05, we will annually interview 4 individuals (see Attachment C: Interview Guide) in each tribe to qualitatively assess what interviewees know and have learned about FL/CP; the extent to which they have incorporated ideas from FL/CP into their programs or classes (managers, staff, teachers) or decision-making (leadership); and if collaboration on substance abuse issues has increased with time through the diffusion processes.
h) In YR01- YR05, TRTs will conduct an annual scan (through interviewing the school and/or youth program key informant, as part of the five interviewees) to identify other substance abuse prevention programs, culture and language programs, or integration of FL/CP cultural components into tribal programs to be able to plot these other resources against the FL/CP impacts. This scan will first take place at baseline. Rather than trying to prevent cross-contamination, we expect there will be diffusion of FL/CP program components as well as increased knowledge by other Health and Education staff and educators to create an environment where FL/CP can be sustainable to improve health and reduce substance abuse over the long term (beyond when the grant ends).
i) Co-analysis of pre/post-test and process evaluations will be conducted
j) Dissemination plan will be co-developed.

12) List of Appendices

Attachment A: Family Program Recruitment Letter
Attachment B: Study Timeline
Attachment C: Tribal Leader and Managers' Interview Guide

13) Data and Specimen Banking

No data or specimens will be banked.

14) Data Management

Upon consent/assent by family participants involving a child (4th grader), parent/guardian the pre/post survey will be conducted in three communities at a scheduled convenient meeting time in a pre-designated tribal facility that will comfortably accommodate the family participant members and the research team members, the meeting room will be closed to the general public to allow for privacy and confidentiality. Dedicated (4 per tribal site) laptop computers will be used in the tribes for data collection and the laptops will be HSC-UNM Novell network NetID protected (valid, unique user identification and privileges). UNM-HSC IT policy requires all users to maintain current authorizations and privileges to ensure maximum-security features are implemented. UNM and Tribal site coordinators will be issued user accounts, as per UNM-HSC IT policy for this purpose. All questionnaire data will be collected via Inquisite web-based assessment software on project laptops. Data collected will be directly uploaded to the questionnaire vendor (Klein-Buendel, Inc., a health communication research firm in Golden, CO) server. Web-based programs are hosted on Klien Buendel's web server, a Dell Power Edge, with two 1.6 Ghz Xeon processors, 4 gigabytes of RAM, and three 72-gigabyte hard drives which operate off a hardware RAID5 system. Sensitive information and material for the project will be stored on this web server, protected by a hardware firewall (Cisco PIX). Each web server has its own native Windows security software. The Klein Buendel server uses a Secure Socket Layer (SSL) 128-Bit Encryption Key. All servers at KB are connected via 1 Gigabit high-speed switched network, insuring high-speed transfer between machines. All computers on the network are protected from viruses by Sunbelt Viper Enterprise. A nightly backup of each computer provides protection against the loss of data. Questionnaire data will be transmitted from KB to project staff via password-protected CDs securely mailed via Fedex. Once received, data will be stored on UNM-HSC secure servers. Only UNM research team members with unique Novell NetIDs and Tribal site coordinators and local tribal evaluators (all with required CITI training) will have access to secured data. Once on the UNM server, all data will be de-identified by individual, except for their tribal membership. Aggregated data will be available to TRTs for interpretation, upon data transmission and database construction (quantitative surveys) in order to minimize risks related to loss of confidentiality. Master databases containing all tribal waves, and aggregate data will be located on UNM-HSC workstations only.

Quality assurance plan

The UNM and tribal research teams will be responsible for data collection. Survey instruments have been adapted from reliable and valid sources from the literature, with

additional items of cultural appropriateness added from TRT input. Survey instruments will be designed for interactive laptop administration.

The research team will log onto the secure password protected laptop to provide access for the adult participant to take the self-administered pre-web-based survey instrument. For the child participant, a local TRT or UNM research team member will again log onto the secure password protected laptop to administer the pre-web-based survey instrument by reading aloud each question to the child, who will have the laptop with the web-based survey to record each response directly onto the web-based survey behind a desk-top partition, assuring privacy. Once the adult and child pre- web-based surveys are completed the research team member will sign out of the program and shut down the laptop. The consent forms will be collected and placed in a separate sealed envelope and will be transported to UNM in Albuquerque and placed in a different locked filing cabinet in the same locked office of the PI for three years, after which time they (consent forms) will be destroyed according to university procedures in the destruction of hard copies of research documents.

The administration of the post-survey will be conducted at the completion of the twelve week two-hour sessions of the FL/CP prevention/intervention program, and 1yr later and will follow the same steps taken in the administration of the pre-survey as outlined above for both the adult and child participant.—A comparison between pre/post and one year post survey will be conducted by t-testing of comparisons. Findings with statistical significance will be reported and an executive summary will be included. The research team will utilize a participatory approach and engage the tribal research team in the interpretation of the initial findings. Data will be interpreted by the UNM and Tribal Research Teams to ensure cultural appropriateness and reflection of the lived experience of community partners. Dissemination of findings for each community will be based on recommendation by the tribal research team. Past research experience with other tribal communities recommended the preparation of powerpoint slides with findings and brief executive summaries to be shared with tribal leadership and program staff.

Qualitative data from program manager and leader interviews will be audio recorded and transcribed verbatim. The files will be read through completely then cleaned for filler utterances. The file will then be converted to rich text file document and uploaded into Atlas.ti qualitative software. Coding will occur inductively and a code sheet developed, themes will be developed from codes, then data will be thematically analyzed.

15) Provisions to Monitor the Data to Ensure the Safety of Subjects

***For all studies considered greater than minimal risk**, include a data and safety monitoring plan (DSMP) for reporting data monitoring committee findings to the HRRC and the sponsor*

See attached DMSP report.

16) Withdrawal of Subjects

Taking part in this study is completely voluntary so participants can choose not to participate or withdraw at any time. If participants choose not to participate in the facilitated sessions or become unable to participate (i.e. unable to get off work), we will still seek to obtain all post and one year post assessments (using an intent-to-treat design).

17) Risks to Subjects

A potential risk that may occur during the twelve weekly two-hour sessions of the Family Listening prevention/intervention program in which session six includes a discussion of recognizing types of anger or session elven on being different, a child or adult may share a troubling experience due to being angry or being different. If needed an individual will be referred to a counselor at the local health clinic. Each tribal community has access to a local tribal behavioral health program at the tribal health clinic. Any costs associated with counseling or other treatment will be the responsibility of the participant. Dr. Kamilla Venner, UNM Psychology Professor will also be available as a consultant to the FL/CP facilitators and tribal behavioral health units as a back-up clinical psychologist.

A potential risk to participants is a loss of privacy, confidentiality, and emotional risk. All reasonable efforts to maintain and protect privacy and confidentiality for all participants will be made by the UNM team. University researchers each have multiple years of CBPR research experience (Dr. Wallerstein, over 25; Mr. Tafoya, over 10; and Dr. Belone, over 14; Ms. Rae, over nine; Dr. Woodall over 15), including human subjects and have maintained CITI certification. The likelihood of loss of confidentiality is low, given the UNM research teams experience with research.

18) Potential Benefits to Subjects

There may be no direct benefit to the individual family participants (parent/guardian, child, or elder family member), however a possible benefit may be improved communication and anger management skills between the parents/guardian, child, and family elder. For the parent/guardian an additional possible benefit may be improved parenting skills. For the child an additional possible benefit may be improved skills in identifying positive social support and an increase self-identification with any of the three tribes by gaining knowledge in history and important teachings. An overall benefit will be the input gained from the participants in the FL/CP twelve week two-hour sessions, the lessons learned by participation will contribute to improvements in the development of an empirically-based and culturally-centered family prevention/intervention program for the three tribes.

19) Vulnerable Populations

Inclusion of Children: There will be at least one child and one parent from each of the 12 participating families in the family-based prevention program and 12 non-participating families in years one, two, three and four. Therefore this project will include a total of 24 child participants per year in each tribal community for a total of 72 children per year (12

child participants + 12 child non-participants) X 3 tribal communities). It is expected 288 children will participate in the FL/CP intervention project over the proposed four-year data collection period.

20) Multi-Site Research

The research takes place in three tribal communities with one University partner, the UNM Center for Participatory Research.

21) Community-Based Participatory Research/Field Research

Our CBPR approach has produced committed collaborative partnerships, which honor the ownership and direction from our Jemez Pueblo, Ramah Navajo and Mescalero Apache partners. Building from previous NARCH pilot grants with these tribes, we have in fact met the NARCH initiative goals: to reduce research mistrust; to develop a pipeline of AI research scientists through the capacity-building of our TRTs (with some interested in future MPH education) and core UNM-CPR Research Scientists; and to develop an intervention with preliminary data that has shown promise to reduce substance abuse disparities, with the R01 as the next step. Our approach has been grounded in well-established CBPR principles of honoring community strengths and long-term commitments [Israel, et al, 1998; Israel, et al, 2012], as well as in indigenous CBPR principles of supporting tribal sovereignty and cultural renewal [Walters, et al, 2009; LaVeaux & Christopher, 2009]. CBPR has been recognized, not only as beneficial for reducing historic mistrust of research and addressing community priorities, but as strengthening translational science that addresses both internal validity as well as external validity to ensure effectiveness across diverse tribal communities [Wallerstein & Duran, 2010; Minkler & Wallerstein, 2008]. As such, CBPR intentionally reflects implementation research concerns of how to best contextualize and culturally-ground interventions [Brownson, Colditz & Proctor, 2012], which is reflected in our tribal-specific versions of FL/CP.

This RO1 therefore: 1) supports multilevel understanding and assessment of the FL/CP prevention effectiveness through a quasi-experimental comparison between intervention and comparison children, with triangulation of quantitative and qualitative impact and process measures, and assessment of both core evidence-based and specific cultural components; 2) strengthens research skills of our tribal colleagues as co- researchers building upon research capacities gained from previous CDC and NARCH funded projects; 3) supports a within-tribe longitudinal (pre-post, 6-month post, and 1-year post) that compares program impacts on 4th grade children, their parents and families; and 4) enables an aggregated sample for testing FL/CP effectiveness with sufficient numbers to achieve statistical significance, given effect sizes for preliminary data; and as a scientific inquiry into the role of CBPR in translational research to reduce disparities in Indian country.

As Cook and Campbell (1979) note, there are a wide variety of factors that make the use of randomization procedures in group designs difficult to impossible, especially in field research settings. In the present case, there are a number of factors at work that make the randomization of participants to either an intervention or usual and customary treatment group not feasible. First, the tribal communities that are participating in the proposed

project are small and close-knit, characterized by highly interwoven social networks [Cook & Campbell, 1979]. As a result, randomly assigning some children and families to the intervention group and not others is problematic because doing so would likely be socially disruptive. Second, the employment of randomization procedures in this setting implies a level of outside political control that is not achievable in tribal communities. These communities have histories of disadvantage and discrimination, and decisions are usually politically closed to those outside the community, research groups included. Third, the norm of collective equity and CBPR processes which honor tribal voice is prominent and strong, and randomization procedures can mitigate against the ethical responsibility to work towards tribal ownership and sustainability once the grant ends [Buchanan, Miller, & Wallerstein, 2007]. We propose therefore the use of a two arm non-equivalent control group design with pretest, immediate post- test, and 12 month follow-up assessment points (see Table 2 below). Among quasi-experimental designs that could be employed, this design carries several advantages over other designs in being able to infer causality [Cook & Campbell, 1979], and we shall follow data analysis procedures recommended by Cook and Campbell concerning this design. One advantage of this design is that it allows for a more meaningful analysis of the impact of the FL/CP intervention by a comparison of the intervention group with the usual and customary comparison group, an advantage not possible with single-group over time designs. Second, the design provides an analysis of diffusion effects (i.e. the potential influence of the intervention on the comparison group over time). Given the tight social networks and small number of interconnected families in the three participating communities, we expect some degree of program diffusion in the comparison group families. We will employ analysis procedures to examine this potential diffusion effect (see below in Aim 3).

Study Personnel – N/A

Location – N/A

Informed Consent – N/A

Procedures – N/A

22) Sharing of Results with Subjects/Incidental Findings

All community-specific results will be shared back to the communities in aggregated form. UNM research team will work with the TRTs to determine the type of format (graphs, tables, pie charts, narrative) is most appropriate for sharing the results back with the community. Aggregated results from all three

communities will be disseminated with guidance and participation from our TRT members through national presentations and publications.

23) Resources Available

The 1R01DA0371740 01 is funded by the National Institute on Drug Abuse, National Institutes of Health. See attached notice of award dated 03/14/2014.

24) Prior Approvals/Attachments Requiring Signatures

Describe any approvals that will be obtained prior to commencing the research. (e.g., school, external sites, funding agency, laboratory, radiation safety, or biosafety approval). Upload the required ***Departmental Review Form*** signed by your department chair (or authorized designee if the PI is the Department Chair) into Click IRB under "supporting documents".

Letters of Support/ Approval have been obtained and are attached from various programs and tribal authorities (including tribal council and other resolutions) of each of the three participating tribal communities as well as the Albuquerque Area Southwest Tribal epidemiology Center and the office of several New Mexico Senators and Representatives.

Study will require simultaneous approval from the Navajo Nation Institutional Review Board and the Southwest Tribal Institutional Review Board.

25) Confidentiality

All reasonable efforts to maintain and protect privacy and confidentiality for all participants will be made by the UNM team. All UNM and lead tribal site coordinators have successfully completed the CITI training and submitted conflict of interest forms. As a principal of CBPR our tribal research partners are to be involved in every stage of this research project. University researchers each have multiple years of CBPR research experience (Dr. Wallerstein, over 25; Mr. Tafoya, over ten; and Dr. Belone, over twelve; Ms. Rae, over nine; Dr. Woodall over 15), and likelihood of loss of confidentiality is low, however, the following procedures will be followed to add extra layers of protection.

Quantitative survey data: Quantitative survey data: Due to the longitudinal pre-post test survey design; linking information will be required. Unique ID numbers for study participants will be a suffix code 3 characters long; the random number generator that comes standard with SPSS software will generate these codes. The first unique code will be sequentially assigned to consent forms. For example the first person to submit a consent form will be assigned to the first random number sequence. Each Unique ID will also have a prefix code 7 characters long; the first character/digit will be the tribal site identifier, the second character/digit will be the wave identifier. The next two characters/digits will be the family identifier (distinguishing intervention and comparison study groups), and final two characters/digits will distinguish whether parent or child population. Data will be

presented in aggregate format (means, medians, standard deviations, effect size) to each TRT for interpretation and subsequent analysis.
Qualitative interview data: all interviews will be transcribed. During transcription identifiers such as names and relations will be stripped from the transcript in order for the respondent to remain anonymous, except for tribal affiliation will be maintained. The UNM and tribal research staff will take the lead in thematically analyzing the data and present it back to the TRT in thematic categories.

26) Provisions to Protect the Privacy of Subjects

Research documents that will be collected are consent/assent forms and they will be collected in the field, once signed or completed the documents will be placed in separate large sealed envelopes. The pre/post-survey will have no names or identifiers other than a numeric number allowing the PI to count the total number of participants. An electronic master list of numeric numbers and child and parent names will be kept in password protected file on Dr. Belone's computer. All completed consent/assent forms will be stored while still in their sealed envelopes in locked filing cabinets in the co-PI Belone's locked office on a locked floor in a locked university building. Sealed envelopes will only be opened by PI of project. The privacy of consent forms for the key informant interviews will be kept confidential, and stored in sealed envelopes in locked filing cabinets in PI Wallerstein's office.

27) Compensation for Research-Related Injury

This is a minimal risk project with sufficient psychological and behavioral services back-up within each community and with a UNM psychologist. We don't expect any research-related injury to occur.

28) Economic Burden to Subjects

N/A

Research Procedures	Number of Samples/Procedures	Responsible Party	
		Study	3rd Party Payer or Participant
N/A	_____		
_____	_____		
_____	_____		
Standard of Care Procedures	**Number of Samples/Procedures**	**Responsible Party**	
		Study	**3rd Party Payer or Participant**
N/A	_____		
_____	_____		
_____	_____		

- List any other costs to participants not already described above.

- Will participants be charged for the costs of an investigational drug/ device/ intervention?
  N/A
- Explain who will be responsible for paying for treatment of adverse events.
  N/A
  Note: If sponsor will be responsible for treatment of research related injury, submit a copy of the Clinical Trials Agreement (CTA) for review.

29) Consent Process (including waiver request for HIPAA, waiver of HIPAA for recruitment only, Waiver of Informed Consent, and Alteration of Informed Consent)

Family Prevention/Intervention Program. The following will be conducted with the child and adult (parent/guardian and/or) who may be potential family participants: a) based on purposeful recruitment and the interest by potential participants a member of the tribal research team will schedule a time convenient for the potential family participants to meet at a designated place that will comfortably accommodate the potentional family and the research team member(s), the meeting room will be closed to the general public (e.g. family home or private work office) to allow for privacy and confidentiality, during this meeting the potential family participants will be able to review the project documents that will be provided prior to consent; b) at the scheduled meeting time with the potential family participants, the tribal research team member will read aloud the consent and assent forms and will also provide a copy for the potential participants to follow along; c) next, a copy of the adult and child pre/post instruments will be provided to allow the potential family participants the opportunity to review and ask questions; d) an outline of the twelve weekly two-hour sessions of the prevention/intervention FL/CP program will be provided. The potential family participants will have time to read all the documents and to ask questions and consider participating. The potential family particpants will be informed of the voluntary nature of the study, as well as the potential risks and benefits and other information described in the consent and assest documents; and finally, e) for those that choose to participate they will sign their consent and assest forms which will be collected and placed in a sealed envelope. After receiving the signed informed consent the parent/caregiver will be given the adult pre-test instrument, which will be self-administered on the secure password protected laptop. A tribal and/or UNM research members will be available should clarification of a question be requested by the participant. The adult post-survey instrument will be self-administered upon the completion of the twelve weekly two-hour sessions of the family prevention/intervention curriculum by adult participants who voluntary to complete. Child pre-tests and post-tests will be administered at the schools or another tribal facility with either a tribal or UNM research team member, using the secure password protected laptops to assure confidentiality. Up to four children at a time can take the tests simultaneously. .

Leaders, managers, educators, and/or staff. The following consent process will be conducted with the adult community leader, manager or staff who may be potential interview participants: a) based on purposeful recruitment and the interest of the potential participant, a tribal research team member will schedule a time convenient for the

potential interview participant to meet for the interview. The interview will be scheduled at a convenient location that will comfortably accommodate the potential participant and research team member. The interview location may be a private office space or other location to allow for privacy and confidentiality; b) at the scheduled meeting time with the interview participant, a tribal research team member will read aloud the consent form and will provide the interview participant with a copy to follow along. The interviewee will be informed of the voluntary nature of the study, as well as the potential risks and benefits and other information described in the consent document; c) after the consent form has been reviewed the potential participant will be asked if he/she has any questions. Questions will be answered and the interviewer will ask if the participant wishes to continue with the interview. If they decide not to participate the interviewer will thank the potential participant for his/her time and leave. If the potential participant wishes to proceed with the interview, the interviewer will ask the participant to sign the consent form, and place the signed consent form into an envelope and seal it. The potential family participants; and finally, d) lastly, the participant will be given a copy of the interview questions to follow along with the interviewer and the interview will commence.

Waiver or Alteration of Informed Consent:

*Will not be requesting an **alteration or waiver of informed consent.***

Waiver of Written Documentation of Consent:

Not requesting a waiver of consent documentation.

HIPAA Authorization

No, will not be collecting PHI.

Waiver of HIPAA authorization:

No will not be requesting a waiver of HIPAA.

Non-English Speaking Subjects

English will be the primary language of the prospective participants.

Planned Emergency Research Consents

N/A

Cognitively Impaired Adults/ Adults Unable to Consent/ Use of a Legally Authorized Representative (LAR)

N/A

30) Drugs or Devices

N/A

Drugs: Please respond to all questions in this section and include a completed and signed Drug Attachment form.

Medical Devices: Please respond to all questions in this section.

N/A

Please complete the section below to determine if an IDE is required:

N/A

Humanitarian Use Device (HUD):

N/A