Protocol v.8
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I. Research Project Title: Alcohol, Marijuana, and Risky Sex: Group Interventions with Detained Adolescents (Project MARS)

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III. Hypothesis/Study Goals (questions hoped to be answered by study)

Substance use is clearly an important behavioral cofactor for HIV and STD infection. Young people under the age of 25 continue to be the segment of the population in the U.S. at highest risk for HIV and other STDs (CDC, 2005). Data presented by the CDC at the 2008 National STD Prevention Conference show that 1 out of every 4 young women aged 14-19 has at least one common STD. Young people of color (CDC 2005; The Allan Guttmacher Institute, 2004), and young people involved with the juvenile justice system (Teplin, Mericle, McClelland & Abram, 2003) are subgroups of adolescents at highest risk for negative outcomes as a result of risky behavior. The relationship of substance use to risky sex appears to be particularly strong for high risk adolescents including those involved in the criminal justice system (Guo et al., 2006; NIAAA, 2006; NIDA, 2004; Wilsnack et al., 1997; Teplin et al., 2005).

In our ongoing intervention work with incarcerated adolescents, we are demonstrating that a sexual risk reduction intervention combined with an alcohol risk reduction component produces increases in safer behavior (i.e., condom use) over and above a sexual risk reduction intervention alone (Schmiege, Broaddus, Bryan et al., 2008). In related work with probated adolescents, we have data that suggest that marijuana use during sexual activity is even more common than alcohol use during sexual activity, and higher levels of problematic marijuana use are associated with higher rates of risky sex. In this proposal, we detail a second randomized controlled trial of an HIV/STD prevention intervention for incarcerated adolescents. Given our success at combining substance use risk reduction in a group motivational enhancement therapy (GMET) format with a sexual risk reduction intervention, and our preliminary studies indicating *both an extremely* high prevalence of marijuana use and an association between problematic marijuana use and sexual risk behavior *in this population*, we propose to compare our sexual risk reduction plus alcohol GMET (SRRI+ETOH) intervention to a *new* sexual risk reduction intervention that includes a GMET with *both* an alcohol risk reduction component *and* a marijuana risk reduction component (SRRI+ETOH+THC). These conditions will be compared to a sexual risk reduction intervention, but, also new to this research, this intervention will be matched by time and treatment modality through the use of a GMET focused exclusively on risky sex (SRRI). The overarching innovations of this research are thus to demonstrate whether the addition of marijuana content enhances the efficacy of the SRRI+ETOH intervention, and to determine whether it is the treatment modality (GMET versus traditional techniques) or the substance use content that is responsible for the efficacy of these interventions. To these ends, the current research has four specific aims:

Specific Aim 1. Extend our previous research by testing the efficacy of a theory-based, empirically targeted sexual risk reduction intervention that targets *both* alcohol *and* marijuana use as risk factors (SRRI+ETOH+THC), as compared to a sexual risk reduction intervention that targets only alcohol use as a risk factor (SRRI+ETOH). Both of these interventions will be compared to a sexual risk reduction only control condition (SRRI) in a sample of ethnically diverse, high-risk adjudicated adolescents.

- **Hypothesis 1.** High-risk adolescents who receive the SRRI+ETOH+THC intervention will have higher rates of condom use behavior at follow-up compared to adolescents who receive the SRRI+ETOH intervention, who in turn, will have higher rates of condom use than adolescents who receive the SRRI intervention.

- **Hypothesis 2.** The SRRI+ETOH and SRRI+ETOH+THC interventions are expected to significantly increase the use of strategies to decrease alcohol-related sexual risk (i.e., carry condoms with you when you will be drinking; have a friend look out for you in case you get too drunk; drink soda/water in between drinks) as compared to the SRRI intervention.

- **Hypothesis 3.** The SRRI+ETOH+THC intervention is expected to significantly increase the use of strategies to decrease marijuana-related sexual risk (i.e., carry condoms with you when you will be smoking marijuana; smoke less marijuana/monitor your marijuana smoking when you're in a situation where you might have sex) as compared to the SRRI+ETOH and the SRRI interventions.

- **Hypothesis 4.** High-risk adolescents who receive the SRRI+ETOH+THC intervention will have lower rates of Chlamydia and Gonnorhea (two common sexually trasmitted infections, or STIs) at follow-up compared to adolescents who receive the SRRI+ETOH intervention, who in turn, will have lower rates of Chlamydia and Gonnorhea than adolescents who receive the SRRI intervention

Specific Aim 2. Deconstruct the mechanisms of change by determining to what extent the effect of the combined interventions on condom use behavior is mediated by changes in proximal constructs (e.g., self-concept, attitudes, intentions, & self-efficacy) from a theoretically-derived and empirically supported model of condom use behavior.

- **Hypothesis 5.** We expect that the superior effect of the SRRI+ETOH+THC as compared to the SRRI+ETOH, and of the combined interventions as compared to the SRRI intervention on condom use behavior and STI outcome will be mediated by the effect of the interventions on model constructs proximal to condom use behavior. Based on our prior intervention work, we expect these differences to be largest for the self-efficacy construct.

Specific Aim 3. Examine whether individual differences in levels of alcohol-related problems and/or marijuana-related problems moderates the efficacy of the combined interventions.

- **Hypothesis 6.** The SRRI+ETOH and the SRRI+ETOH+THC interventions are expected to demonstrate even greater efficacy for those adolescents who have greater problems with alcohol, but will not demonstrate greater efficacy for those individuals who do not have problems with alcohol.

- **Hypothesis 7.** The SRRI+ETOH+THC intervention is expected to demonstrate even greater efficacy for those adolescents who have greater problems with marijuana, but will not demonstrate greater efficacy for those individuals who do not have problems with marijuana.

Specific Aim 4. Test whether genetic factors (e.g., DRD4) previously linked to neurocognitive components of risk-taking behavior (e.g., response inhibition, delay discounting, risky decision making) moderate the effectiveness of the interventions.

- **Hypothesis 8.** Intervention effects will be stronger for DRD4S individuals and weaker for DRD4L individuals.

To summarize, we hypothesize that rates of condom use will increase and rates of STI infection will decrease most among adolescents who receive the SRRI+ETOH+THC intervention (targeting both alcohol and marijuana use as risk factors), followed by adolescents who receive the SRRI+ETOH intervention (targeting only alcohol use as a risk factor), and finally adolescents who receive the SRRI intervention (sexual risk reduction only) will increase their condom use the least and have the highest incidence of STIs. We also hypothesize that the SRRI+ETOH and SRRI+ETOH+THC interventions will decrease alcohol-related sexual risk behaviors compared to the SRRI intervention. Further, the SRRI+ETOH+THC intervention should decrease marijuana-related sexual risk behaviors compared to the SRRI+ETOH or SRRI interventions. We also expect that the effects of the interventions on condom use and STI incidence will be mediated by constructs proximal to condom use behavior (e.g., self-efficacy). Additionally, the effectiveness of the SRRI+ETOH and SRRI+ETOH+THC interventions will be conditioned by alcohol problems and marijuana problems such that the interventions will be more effective for individuals with these respective problems. Finally, we hypothesize that the intervention effects will be conditioned by genetic factors such that the intervention will be stronger for individuals who carry various protective alleles (e.g., DRD4S) and weaker for those who carry risk alleles (e.g., DRD4L).

IV. Background

i) Existing Knowledge

Due to high rates of unprotected intercourse with multiple partners, adolescents are at great risk for sexually transmitted diseases (STDs) including the human immunodeficiency virus (HIV)(CDC, 2000a; Dilorenzo & Hein 1995; Koniak-Griffin, Nyamathi, Vasquez, & Russo, 1994; Whaley, 1999). Though the CDC (2005) reports that overall AIDS incidence is on the decline, there has been an increase in the number of newly diagnosed HIV cases among young people aged 15 to 24. Further, the highest rates of many common STDs (e.g., chlamydia) occur in young people between the ages of 15 and 23 (CDC, 2000b). Of the estimated 18.9 million new STD infections in the United States in 2000, nearly half occurred in people between the ages of 15 and 24 (Weinstock, Berman & Cates, 2000). Data presented by the CDC at the 2008 National STD Prevention Conference show that 1 out of every 4 young women aged 14-19 has at least one common STD (http://www.cdc.gov/stdconference/2008/media/release-11march2008.pdf). In comparison to the general adolescent population, adolescents involved with the criminal justice system—who are disproportionately of color—are younger at first intercourse, have higher rates of anal intercourse, a greater number of sex partners, and lower rates of condom use (Barthlow, Horan, DiClemente, & Lanier, 1995; Lux & Petosa, 1995; Morris, Harrison, Knox, Tromanhauser & Marquis, 1995; Teplin, Mericle, McClelland & Abram, 2003). These risky sexual behaviors result in high rates of unintended pregnancy and STDs among criminally-involved adolescents (Canterbury, Clavet, McGarvey & Koopman, 1998; Morris et al., 1995; Morris, Baker, Valnetine, & Pennisi, 1998; St. Lawrence et al., 1999). Substance use is a critical risk factor for unprotected sexual behavior, and the available data suggest that the relationship of substance use to sexual risk is strongest

for adolescents (Guo et al., 2006; NIAAA, 2006; NIDA RFA-DA-04-012, 2004; Wilsnack et al., 1997; Teplin, 2005; Testa & Collins, 1997). Alcohol use and misuse is highly prevalent among adolescents and young adults, such that 82.5% of individuals ages 15-24 report a history of alcohol use, 16.5% of whom meet DSM-III-R criteria for alcohol dependence (Anthony et al., 1994). Adolescents who are involved with the criminal justice system are at even greater risk than their non-criminally involved peers (Ho, Kingree, & Tompson, 2006), with an estimated 88.7% of incarcerated adolescents reporting current use of alcohol (Lebeau-Craven et al., 2003) and 47% meeting DSM-III-R criteria for an alcohol use disorder (Neighbors et al., 1992). A recent study published in JAMA finds similarly high and increasing levels of marijuana use among adolescents (Compton et al., 2004), and the use of marijuana is strongly associated with involvement in the criminal justice system (Ho et al., 2006; Kingree, Braithwaite, & Woodring, 2000). New Mexico (NM) is a key location to examine the confluence of drug use and sexual risk behavior, as both rates of substance use and negative consequences of use, as well as sexual risk behavior are extremely high. The alcohol-induced death rate in NM from 2003-2005 was 17 deaths per 100,000 people; 141% higher than the national rate. The drug-induced death rate was 18.9 deaths per 100,000 people; nearly twice the national rate of 9.9. These rates are for deaths directly attributable to substance use (i.e., do not include MV crashes, accidents, or disease exacerbation). Though the HIV/AIDS prevalence rate is comparatively low (36th out of 50 states), NM ranks 3rd out of the 50 U.S. states in rates of Chlamydial infections (444.3 per 100,000 persons), and the vast majority of those cases are among adolescents and young adults, suggesting an extremely high rate of unprotected sex among NM adolescents. Data from the CDC Youth Risk Behavior Surveillance System suggest that young people in New Mexico are slightly riskier than those in Colorado. For example, 26% of young people in New Mexico used marijuana in the last 30 days, compared to 23% of Colorado youth. 33% of NM youth had sex in the last 3 months, compared to 29% in CO, and in both states 26% of sexually active youth reported using alcohol or drugs prior to their last sexual intercourse. Thus, we expect the same or higher rates of risk behavior in NM criminally-involved young people as we found in CO. Further, our community collaborators in the NM juvenile justice system confirm that rates of marijuana use are far and away higher than use of any other drug, and because of its ease of acquisition for adolescents, typically higher than rates of alcohol use.

Given the extremely high rates of sexual risk behavior, alcohol use, and marijuana use among criminally-involved adolescents, the theoretical and empirical link between substance use and risky sex, and our preliminary data supporting the efficacy of incorporating content specifically focused on the reduction of alcohol-related sexual risk behavior, we propose to extend our prior work to include an approach to HIV risk reduction interventions with criminally involved adolescents that acknowledges that the two most common drugs of abuse in this population are marijuana use and alcohol use. We believe that an intervention that targets the full spectrum of the most common and interconnected risk behaviors among criminally-involved adolescents (sexual risk, alcohol use, and marijuana use) has the potential to serve as a guiding framework for risk reduction intervention technology for this population of highly vulnerable youth. The following sections review prior research on the relationship of alcohol to HIV sexual risk, the relationship of marijuana to HIV sexual risk, and the use of group motivational enhancement modalities, and then focuses on the integration of these ideas and the logic of the proposed hypotheses.

Alcohol Use and Risky Sex. The empirical relationship of alcohol to risky sex is complex and may take different forms for different individuals and contexts (Cooper, 2006). Cooper (2002) concluded that alcohol use was strongly associated with decisions to have sex and with indiscriminate forms of sexual risk-taking (e.g., sex with casual partners) but was not consistently associated with protective behaviors

(e.g., condom use). Inconsistencies of empirical data on the subject may plausibly be due to diversity of methodological approaches in addressing this question. The association between alcohol and risky sexual behavior has primarily been examined in three ways: (1) global correlation, (2) situational covariation (also called time-limited global correlation), and (3) event analysis (Halpern-Felsher et al., 1996). Global correlation studies and time-limited global correlation studies generally find a negative relationship between alcohol use and condom use (e.g., Duncan, Strycker, and Duncan, 1999; Halpern-Felsher et al, 1996), however these studies are vulnerable to third variable influences and problems with inferring causality. Studies utilizing an event analysis or episodic methodology, when they show an association between alcohol use and risky sexual behavior, are the most convincing evidence that alcohol use proximally influences condom use. The results of such studies, however, have also produced conflicting findings (Leigh & Stall, 1993; Leigh, 2002; Weindhardt & Carey, 2000). Tubman and Langer (1995) found no reliable association between condom use and alcohol use among adolescents in substance abuse treatment, while Dermen, Cooper, and Agocha (1998) found that alcohol use was positively associated with an HIV risk index at three intercourse occasions among a random sample of adolescents. Laboratory alcohol administration studies do tend to show that alcohol intoxications leads individuals to report higher willingness to engage in unprotected sex (e.g., Abbey et al., 2006). In a recent review of event-level studies, Weinhardt and Carey (2000) highlighted potential moderators of the relationship between alcohol use and risky sex, such as personality traits, sex-related alcohol expectancies, and gender. In summary, results on the association between alcohol use and sexual risk taking are inconclusive and may vary as a function of level of analysis (Halpern-Felsher et al, 1996), type of risky behavior (Cooper, 2002), relationship type (Brown & Vanable, 2007; Halpern-Felsher et al, 1996; Vanable et al., 2004), population under study (Donavan & McEwan, 1995), and type of sexual encounter (Leigh, 2002). In order to reconcile conflicting results, recent studies have begun to examine potential moderators of the relationship between alcohol and risky sex. For example, Corbin and Fromme (2002) found that the association between alcohol use and condom use among college students was strongest for the first sexual encounter with a partner and was moderated by expectancies of alcohol-related sexual enhancement (Corbin & Fromme, 2002). Our prior NIAAA-funded work with probated adolescents (RO3 AA12925-01) demonstrated results that largely mirrored the findings of Corbin and Fromme (2002). In Bryan, Ray, and Cooper (2007), we found that the strongest association of alcohol use to condom use among probated adolescents occurred at the event level. As number of drinks consumed prior to an intercourse occasion increased, odds of using condoms decreased, supporting the inclusion of situation-specific alcohol risk reduction content in HIV/STD prevention activities for these adolescents.

Marijuana use and Risky Sex. Over approximately the past decade, there has been an increase in awareness regarding the growing prevalence of marijuana use and the deleterious effects that result from its use. A U.S. National Household Survey on Drug abuse (Epstein, 2002) suggested that 2.8 million Americans met criteria for marijuana abuse or dependence, a number that was greater than for all other illicit drugs combined (Epstein, 2002). Marijuana use is associated with the development of comorbid psychopathology (e.g., depression, anxiety, conduct disorder, AD/HD, schizophrenia, abuse of alcohol and other drugs), alters developmental processes, exacerbates or increases the risk of respiratory disease, increases the risk of a motor vehicle accident and, importantly for the purposes of this proposal, increases the risk of sexually transmitted diseases by facilitating risky sexual behavior (for a review see Dennis et al., 2002; Hall & Babor, 2000). Marijuana use is particularly common among adolescents. A survey of 12th graders in 2000 found that half (49%) reported ever having used marijuana or hashish (Johnston, O'Malley, & Bachman, 2001), and Compton et al. (2004) showed that marijuana use has

increased most dramatically in the past decade among adolescents, particularly among black and Hispanic adolescents. Adolescents involved with the criminal justice system have extremely high rates of marijuana use (e.g., Lebeau-Craven et al., 2003) and are more likely than non-criminally involved adolescents to currently use marijuana (Kingree & Betz, 2003; *Rosengard et al., 2006*). The criminally-involved adolescent participants in our current NIAAA-funded randomized controlled trial, as well as in our current NIDA-funded study, also demonstrate extremely high rates of marijuana use. Fully 92% of participants in the NIAAA study drink alcohol, smoke marijuana, or both, but comparatively fewer use hard drugs (e.g., 4% reported regular (at least once a month) methamphetamine use and 9% reported regular ecstasy use). Furthermore, 40% of participants in this sample report smoking marijuana daily or almost daily. This is in contrast to 5% of those who report drinking daily or almost daily. Similar patterns of use among NM youth in detention were confirmed by our NM collaborators.

The research linking marijuana to risky sexual behavior is not as well-developed as the literature examining the role of alcohol in risky sexual behavior. However, there is some evidence to support a significant deleterious effect of marijuana use on cognitive processes including reaction time, attention, memory, and visuospatial processing, as well as on reasoning and cognitive flexibility (Hart et al., 2001). Notably, there is increasing evidence that marijuana use results in increased risky decision-making (Lane, Cherek, Tcheremissine, Lieving, & Pietras, 2005) and has specific effects on memory and mental flexibility (Lamers, Bechara, Rizzo, & Ramaekers, 2006). Recent work by Gruber and Yurgelun-Todd (2005) utilizing fMRI suggests that marijuana smokers with recent drug exposure demonstrate alterations of the neural circuitry underlying inhibitory function, and altered processing strategies during the completion of behavioral tasks. There is also some evidence that the functional effects of marijuana on decision-making diverge in some ways from the effects of alcohol. For example, Lane, Yechiam, and Busemeyer (2006) demonstrated that while alcohol differentially increases risky decision-making associated with motivation (i.e., gains and losses), marijuana differentially increased risk-taking that was associated with learning and memory.

There are self-report data that connect marijuana intoxication to increased sexual arousal. Green, Kavanagh, and Young (2003) noted that 33.2% of participants reported increased sexual arousal occurring during marijuana intoxication. Further, Kingree and Tompson (2007) found that positive sex-related expectancies were stronger for marijuana than for alcohol in a sample of juvenile detainees, and that such expectancies were related to the use of marijuana during sex. The association between marijuana use and risky sexual behavior, as with alcohol, appears strongest among adolescents. In a longitudinal study of adolescents between ages 10 to 21, Guo et al. (2002) found that individuals who used marijuana were more likely to engage in risky sexual behavior, and in a longitudinally study beginning in the 8th grade reductions in growth in both alcohol use and marijuana use were associated with decreased risky sexual behavior (Griffin, Botvin, & Nichols, 2006). Among adolescents at an STD clinic, those who self-reported marijuana use were twice as likely to be diagnosed with an STD after screening (Liau, et al., 2002). Boyer et al. (1998) reported that high school students who tested positive for marijuana use were more likely to test positive for chlamydia and gonorrhea, and were less likely to report condom use in the preceding six months. The relationship of risky sexual behavior and marijuana use has also been examined among criminally-involved youth. In a study of 153 adolescent male and female detainees, Kingree, Braithwaite, and Woodring (2000) assessed the relationship between marijuana and risky sexual behavior using global, situational, and event-level analyses. At all levels of analysis, there was a significant association between marijuana use and risky sexual behavior. In a similar study, Kingree and Betz (2003) demonstrated strong associations between marijuana and risky sex, but not between alcohol and risky sex. Kingree and Betz (2003) found that marijuana use was extremely common, and in fact a higher percentage of participants reported marijuana use (45%) than

alcohol use (11%) in the context of a sexual encounter. They took an event-level approach to specifically examine the most recent sexual encounter with a current partner. They found that marijuana use (but not alcohol use) during this encounter was associated with failure to discuss HIV/STD risk with the partner and with failure to use condoms.

Our NIDA-funded longitudinal study of the relationship of marijuana use to risky sexual behavior among probated adolescents shows interesting results. We find a global negative relationship between condom use and having used marijuana in the past six months, $r(541) = -.12$, $p < .01$, as well as with frequency of marijuana use $r(536) = -.11$, $p < .01$, indicating that greater marijuana use is associated with lower condom use. Marijuana dependence was also associated with condom use for females, $r(176) = -.15$, $p < .05$), but not for males, $r(410) = -.01$, n.s.. At the event level, there was no overall evidence for a relationship of marijuana use to risky sexual behavior: 64.1% of participants used a condom at last intercourse if they had not been smoking marijuana compared to 63.7% of participants who used a condom if they were smoking marijuana. This pattern did depend, however, on a combination of the participants' gender and whether the participants' marijuana use was discrepant from their partners' marijuana use and relationship status. For males, 32.1% reported using condoms if they were not smoking marijuana but their partner was compared to 64.4% if they were smoking and their partner was not. The pattern for females was the opposite, such that 45.16% used condoms if they were not smoking but their partner was, compared to 20% if they were smoking and their partner was not. In a logistic regression model predicting condom use at last intercourse, the interaction between gender and marijuana use discrepancy was significant, B = -2.53 (1.28), OR = .08 with 95% CI > .01 to .98. Thus the pattern of discrepancy is significantly different for males versus females, and suggests that when the female in the interaction is smoking marijuana and the male is not, condom use is particularly unlikely. These episodic relationships also appear to depend on relationship status such that for those whose last intercourse episode was with someone they had just met, 54% reported using a condom if they had been smoking marijuana, compared to 67.4% who reported using a condom if they had not been smoking marijuana. Marijuana use does not seem to impact risky sex with either casual partners or steady partners to the same degree.

In sum, the existing empirical literature with adolescents demonstrates associations between marijuana use and risky sex. In addition, our data with criminally-involved adolescents show that individuals with higher rates of problematic marijuana use are less likely to use condoms and that the relationship of marijuana use to risky sexual behavior may depend on gender and relationship type. Further, the prevalence of marijuana use is high, and this is particularly the case among criminally-involved minority youth. These data support the inclusion of marijuana-related content in HIV/STD risk reduction interventions for criminally-involved youth.

HIV/STD Prevention Interventions with Incarcerated Adolescents. Reviews of the HIV prevention literature targeting specific groups (e.g., at-risk women, Exner, Seal, & Ehrnhardt, 1997; heterosexual men, Exner, Gardos, Seal, & Ehrhardt, 1999; adolescents, Jemmott & Jemmott, 2000; persons with severe mental illness, Kelly, 1997) as well as more general reviews (Albarracin 2006; Albarracin et al., 2005; Fisher & Fisher, 1992; 2000; Institute of Medicine [IOM], 2000; McKay, 2000) have led to the refinement of a set of criteria under which interventions successfully reduce sexual risk behavior across populations. The characteristics of HIV/STD prevention interventions that successfully change behavior include: deriving interventions from empirically supported theoretical models, including a component targeting condom use self-efficacy and behavioral skills for condom use, a focus specifically on encouraging condom use (as opposed to "risk reduction" more generally or abstinence), and targeting intervention content to the population with whom one is intervening. This targeting includes both

tailoring content to the developmental stage of the population and assuring that the intervention is culturally appropriate. In the PIs previous work with college women (Bryan et al., 1996), inner-city high school students (Fisher et al., 2002), and most recently incarcerated adolescents (Schmiege et al., 2008) this precise combination of factors resulted in substantially higher condom use reported among intervention participants than among control participants. These same factors will be carefully implemented in the proposed work.

There have been a number of HIV prevention interventions conducted with adolescents, with most occurring either in school settings (e.g., Coyle et al., 1999; Fisher et al., 2002) or in community-based settings (e.g., Jemmott, Jemmott, & Fong, 1998; Jemmott, Jemmott, Fong, & McCaffree, 1999) including public health clinics (Quirk, Godkin, & Schwenzfeier, 1993). Despite the literature citing criminally-involved youth as being at high risk of HIV, STDs, and unplanned pregnancy, there are comparatively fewer interventions targeting this population. While this may be due to the perceived difficulty of conducting theory-based, empirically rigorous intervention research in the context of the criminal justice system (c.f., Bryan, Robbins, Ruiz, & O'Neill, 2006), the lack of programs designed for these young people is a clear gap in the national HIV prevention intervention portfolio (IOM, 2000). Schlapman and Cass (2000) developed an intervention based on the AIDS Risk Reduction Model (Catania, Kegeles, & Coates, 1990) and implemented this program at a juvenile detention center in Indiana. A total of 196 adolescents saw at least one session of the four-session intervention. There was no control condition, and efficacy was assessed via comparing pretest to posttest. There were no changes in participants' reported commitment to change their behaviors, and no behavioral follow-up measures were obtained. Clark et al. (2000) conducted a theory-based intervention with 99 incarcerated youth, and showed positive changes from pretest to posttest in intentions to decrease risk behaviors. These preliminary results are encouraging, but this study was also limited by the lack of any behavioral follow-up data and no control group.

The final detention-based intervention is methodologically superior to other interventions. St. Lawrence et al. (1999) compared a sexual risk reduction intervention to an attention placebo control (anger management) intervention in a randomized controlled trial. Adolescents were followed six months post-release, and an 89% follow-up rate was obtained. The sexual risk reduction intervention was a tailored version of St. Lawrence et al.'s (1995) theory-based "Being a Responsible Teen" (BART) intervention identified by the CDC as one of the sexual risk reduction "Programs that Work" for adolescents (CDC, 2000c). Immediate posttests indicated increased HIV knowledge, more positive condom attitudes, and increased condom use self-efficacy in the sexual risk reduction condition as compared to control. However, no differences in behavior by condition were shown at six-month follow-up. Youth in both conditions showed decreased risk behavior (from baseline) and lower frequencies of being in high-risk contexts. The authors note that the detention facility was a strict boot camp model where young people had their head shaved, marched in line, etc. So, it is possible that the environment itself "may be a powerful change agent" (St. Lawrence et al., 1999; p. 16). It may also be possible that during the time youth were incarcerated, there was diffusion across conditions such that participants shared with others what they had seen and done in their respective interventions.

There exist many examples in the research literature of HIV/STD prevention interventions that are conducted with individuals who have substance abuse disorders. Most notably are programs targeting high-risk needle use among intravenous drug users (e.g., Schilling, El-Bassel, Hadden, & Gilbert, 1995). In addition, there are examples of HIV prevention interventions conducted with individuals who are in treatment for substance abuse disorders (e.g., McMahon, Malow, Jennings, & Gomez, 2001; Kwiatkowski, Stober, Booth, & Zhang, 1999; see Prendergast, Urada, & Podus, 2001 for a meta-analytic review). St. Lawrence, Crosby, Brasfield, and O'Bannon (2002) tested the additive components of the

information-motivation-behavioral skills model (IMB) in a population of drug dependent adolescents (mean age was 16, and 75% of adolescents were Caucasian). Participants were assigned to one of three conditions: 1) Information only (I), 2) Information and behavioral skills training (IB), or 3) Information, behavioral skills training, and motivation (IMB). Participants (n = 161) received 12 sessions in a randomized controlled trial in which interventions were conducted in addition to normal drug treatment programs within a treatment facility. Behavioral data were obtained six and twelve months following administration of the intervention. All three groups demonstrated increases in HIV knowledge, and the IB and IMB conditions demonstrated improved attitudes, social competency, and less risky sexual behavior at both follow-ups.

There are relatively few interventions that target both substance use and sexual risk reduction in groups who are not necessarily in treatment for either of these problems. One intervention program has been pilot-tested in HIV-positive youth that takes a motivational enhancement therapy approach to reduce problematic behaviors including unprotected sex and substance abuse (Naar-King et al., 2006). Nineteen participants received individual sessions tailored to their two most problematic behaviors based on baseline measures, but functionally, only 1 participant reporting using a drug other than alcohol and marijuana in the previous 12 months, so it was those two substances that were the focus. While the intervention showed a positive effect on condom use and viral load compared to control group, there were no effects on alcohol or marijuana use. The most promising evidence for the inclusion of substance use content in sexual risk reduction interventions comes from Griffin, Botvin, and Nichols (2006). They conducted a randomized school-based substance use prevention program with adolescents (30 sessions were administered from 7th to 9th grade). Results of long-term program effects (measured ten years following administration of the program) demonstrated effects on alcohol use and marijuana use, such that reductions in growth in alcohol and marijuana use (but not drug use generally) were associated with lower rates of risky sexual behavior.

In summary, while the literature with respect to sexual risk reduction interventions is vast, relevant data are only beginning to emerge to guide efforts to incorporate substance use risk reduction into these interventions. In addition, few studies have evaluated the efficacy of sexual risk reduction interventions in adolescents involved in the criminal justice system, despite the fact that these adolescents are at greater risk for HIV, STDs, and have higher rates of substance use and abuse. Our current study shows promise for the integration of substance use content within a larger HIV/STD risk reduction intervention, however that study only integrated alcohol content, and all the available data indicate that marijuana, but not other drugs, is used with equal or even greater frequency than alcohol across a range of high risk adolescents. Given that even more incarcerated youth use marijuana than use alcohol, and given the suggested link between marijuana use and sexual risk behavior, a strategy that includes **both** of these substances in an HIV prevention intervention has great potential for broad influence across arguably the three behaviors in which these young people engage with greatest frequency and which have clear implications for future health—risky sexual behavior, alcohol use, and marijuana use. One might wonder whether, instead of limiting the content to alcohol and marijuana use, we don't propose a more broad-based "sobriety" intervention or focus on whichever drug a young person uses. We see our approach of focusing on alcohol and marijuana as having both the broadest applicability to our target population and being superior in terms of parsimony. Our rationale for adding marijuana content to our combined alcohol use/risky sex intervention (SRRI+ETOH) centers on four key issues. First, marijuana is the most common drug of abuse among criminally involved adolescents in all regions of the country for which data are available (National Institute of Justice, 2000; Lebeau-Craven et al., 2003), in our recently completed trial of detained adolescents, in a current sample of probated adolescents, and in the New Mexico youth with whom we seek to work. Second, both NIDA and the research community who

study criminally involved youth document that marijuana in particular (as opposed to alcohol use or substance use generally) may be a specific risk factor for engaging in unprotected intercourse (e.g., Kingree & Betz, 2003). Third, our preliminary longitudinal data suggest that marijuana use may be more strongly related to risky sex than alcohol use. A primary reason for why we do not focus on "sobriety" in general is that we do not view our interventions as substance use treatment. As desirable a goal is it may be, a brief intervention is unlikely to impact long-term sobriety. Rather, our brief intervention is intended to target the most common drugs of abuse that we know are likely to be used in conjunction with sexual activity and to reduce the HIV/STD risk associated with those activities. Finally, we know of no evidence suggesting that a "general sobriety" intervention would be effective, likely due to different contexts of use, mechanisms of action, and social and psychological motivations for different drugs of abuse.

In terms of why we do not propose a "drug of choice" approach, we are not hopeful of the success of such an approach for two reasons. First, different drugs of abuse have different mechanisms of action both generally and in their association with risky sex, and thus the content of such a general intervention would have to include every possible mechanism for each individual drug. We have chosen to focus on alcohol and marijuana use because our data suggest that an intervention covering these two topics would be applicable to fully 92% of our detained adolescent population (who use alcohol or marijuana or both). While we agree that other drugs are used sporadically and at low rates in this population (e.g., 4% reported regular (at least once a month) methamphetamine use and 9% reported regular ecstasy use), adding a focus on these specific drugs that would be applicable to these small proportions of the population would not be an appropriate use of intervention time in this context. We also carefully reviewed the drug use literature to make sure that our adolescents are not in some way unique among the larger universe of criminally-involved adolescents, and this does not appear to be the case. For example, a recent study noted consensus across the literature that in the criminally-involved adolescent population less than 7% have used/use methamphetamines (Miura et al., 2006), that alcohol and marijuana are both related to the sexual risk behavior of criminally-involved adolescents , and that alcohol and marijuana use content out to be included in sexual risk reduction interventions for this population (e.g., Rosengard et al., 2006). In addition, there are developmental reasons for focusing only on alcohol and marijuana. Research shows that the age of initial use of methamphetamines and other hard drugs is later than for marijuana and alcohol. For example, in a study of young people entering drug treatment facilities, the average age of methamphetamine initiation was 19 (Brecht et al., 2007). The adolescents we target are 14 to 17.

The Use of Group Motivational Enhancement Techniques. Because it emphasizes concepts such as motivation to change, empathy, and self-efficacy (among other concepts) and because it can be conducted in a group setting, motivational enhancement therapy (MET) is one approach to substance use risk reduction that is consistent with effective sexual risk reduction interventions. MET is an adaptation of the technique of motivational interviewing developed by Miller and colleagues (Brown & Miller, 1993; Miller & Sanchez, 1994; Miller et al., 1988; Rollnick et al., 1992), a technique that has received continuing and significant empirical support in the context of successful, brief behavior change interventions with alcohol and drug abusers (Wylie et al., 1996), smokers (Morgan et al., 1998; Rollnick et al., 1997), diabetics (Stott et al., 1995), and individuals with eating disorders (Long & Hollin, 1995). Brief motivational interventions based on these techniques have also been recommended (Masterman & Kelly, 2003) and successfully utilized for the reduction of alcohol use and alcohol problems with adolescents (c.f., Monti, Barnett, O'Leary, & Colby, 2001; Marlatt et al., 1998). There are emerging data to suggest that the MET approach can also be used to reduce risky sexual behavior (Carey & Lewis, 1999; Picciano, Roffman, Kalichman, Rutledge, & Berghuis, 2001; Naar-King et al., 2006). As

described by Miller et al. (1988), motivational interviewing techniques involve a powerful client-centered form of counseling which emphasizes giving objective feedback to clients about their risk behavior, while providing clear support for change. The client is encouraged to discuss the pros and cons of their current behavior, and is guided to develop ambivalence regarding their current level of risk. When clients determine change is desirable, they are asked to choose a safer behavioral goal to try to achieve and a strategy for attaining it. Allowing individuals to choose a behavioral goal and a preferred strategy for attaining it is regarded as an important component of MI (Miller & Sanchez, 1994). MI techniques also include the enhancement of self-efficacy for behavior change through such activities as role-plays and rehearsals of behavioral skills to be used to effect risk reduction (Bandura, 1994; Rollnick et al., 1992). MET approaches expand on traditional MI with the inclusion of written "feedback" for clients (Hettema, Steele, & Miller, 2005; Miller et al., 1992), and thus our approach in the current and proposed studies is most closely aligned with brief MET. Recently, there has been increasing interest in the possibility of generalizing MI techniques to a group context and there are a small number of studies of which we are aware (e.g., Foote et al., 1999; LaBrie, Pedersen, Lamb, & Quinlan, 2007; John, Veltrup, Driessen, Wetterling, & Dilling, 2003; Michael, Curtin, Kirkley, Jones, & Harris, 2006; Santa Ana, Wulfert, & Nietert, 2007; Van Horn & Bux, 2001; and our own NIAAA-funded study) that indicate promise for the efficacy of group MET approaches. In addition, MI approaches have shown exceptional promise for adolescents in general, and recent work has also provided preliminary support for the use of MI based interventions with criminally involved adolescents (Stein et al., 2006a, 2006b). Group MI/MET approaches may be particularly suited to interventions with incarcerated adolescents (Feldstein, & Ginsburg, 2006) because (a) entry into the justice system may be considered a "teachable moment" when adolescents may be more receptive to contemplating the negative aspects of a behavior, and contemplating avenues of behavior change and (b) our experience with this population leads us to believe that the non-confrontational and supportive approach of MI/MET is an excellent developmental and temporal fit for adolescents involved in the justice system.

This brings up an important point related to the study we recently completed. We find significantly greater changes in theoretical model constructs (e.g., perceptions of normative support for condom use and self-efficacy for condom use) and higher levels of actual condom use behavior at follow-up in the SRRI+ETOH condition as compared to the sex-only (SRRI) and information-only control conditions. One of the differences between the SRRI+ETOH condition and the SRRI condition is clearly content: the SRRI+ETOH intervention incorporates information on alcohol risk reduction in the context of sexual behavior. But the other difference between the two conditions is that the SRRI+ETOH condition incorporates the group motivational enhancement modality, complete with feedback sheets related to one's own level of alcohol use compared to one's peers and the biological effects of alcohol use. In short, the SRRI+ETOH intervention incorporates all the tenants of group motivational enhancement therapies, while the SRRI intervention is a more traditional didactic presentation and discussion of sexual risk reduction. While we believe, based on theory and our preliminary data from the current study, that the superior efficacy of the SRRI+ETOH intervention is due to its incorporation of content specifically focused on the reduction of substance use concurrent with sexual activity, our design in the previous study is clearly vulnerable to the criticism that perhaps it is simply that a group motivational enhancement modality is more effective than a traditional didactic approach. To redress this limitation, this study will incorporate the group motivational enhancement modality into all three interventions. Thus, when we find superior efficacy of the substance use + sexual risk interventions as compared to the sexual risk interventions alone, we will have strong evidence that it is the substance use content, and not the intervention modality, that is driving our effects. On the other hand, if we find that a sexual risk reduction intervention in a GMET format is equally as effective as either of the interventions including

substance use content, this simplifies intervention technology for this population tremendously.

Genetic Factors. Recent work has identified specific genetic mechanisms that may be associated with high risk behaviors. In particular, the dopamine D4 receptor gene (DRD4) is one such indicator (Swanson et al., 2007). Meta analyses indicate that a specific polymorphism within this gene, a 48 base pair variable number of tandem repeats (VNTR), is associated with risk for ADHD (Swanson et al., 2007). Findings from more sophisticated studies suggest that the 7 repeat allele of the DRD4 VNTR is associated with "behavioral excesses" among adolescents with ADHD (Swanson et al., 2007), with greater commission errors (Manor et al., 2001), and greater difficulty in inhibiting responses with a bias toward speed over accuracy (Langley et al., 2004).Some individuals may have a basic biological vulnerability predisposing them to impulsive and risky decision making, which in turn influences the likelihood that they will engage in high risk behaviors such as alcohol- or drug-use related unprotected sexual behavior. Individuals with this basic biological vulnerability may be less likely to respond to interventions to change such behavior that are built on purely psychosocial models.

To summarize, the existing data demonstrate that an attempt to reduce global substance use outside the context of a sexual encounters is unlikely to have a strong impact on sexual risk behavior, given that there are unreliable global associations of both alcohol and marijuana use to risky sexual behavior. On the other hand, an exclusive focus on increasing condom use, without discussion of particular situations that are likely to make condom use more difficult (i.e., alcohol or marijuana intoxication) is also unlikely to optimally affect the substance use-risky sex relationship. A focus on sexual risk reduction AND substance use risk reduction in the context of sexual encounters may be necessary to influence the link between substance use and risky sexual behavior. For criminally-involved adolescents, the most parsimonious approach is clearly to target the two most common substances of abuse: marijuana and alcohol. An intervention with a focus on the link between these two substances of abuse is applicable to fully 92% of the criminally involved population who use alcohol, marijuana, or both. Thus, based on our review of the available literature, our extensive data on and experience with our target population, and the logistical and practical constraints of our intervention population and context, we conclude that the next programmatic and logical step is to test the efficacy of an intervention that combines sexual risk reduction along with alcohol and marijuana risk reduction. A demonstration of the superiority of an intervention that focuses on the reduction of alcohol- and marijuana-related risky sexual behavior would be theoretically, empirically, and pragmatically meaningful in the context of reducing the negative outcomes of risky sex in this population.

ii) Rationale for performing the research

The specific aims of the current study involves extending our previous work to understand a) whether targeting the two most common substances of abuse among high risk adolescents (alcohol and marijuana) increases the efficacy of an HIV/STD risk reduction intervention, b) whether marijuana use content can effectively be included in a sexual risk reduction intervention, c) whether it is the substance use content in particular or the group motivational enhancement modality that is driving intervention effects, d) whether the effectiveness of including substance-use content is moderated by the current substance use status of these young people, e) whether the effectiveness of these risk-reduction interventions is moderated by genetic factors that have been previously linked to assessments of impulsivity (e.g., DRD4), and f) whether the effectiveness of these interventions is moderated by race/ethnicity, gender, and the subjective responsiveness of the young people to the intervention. In order to answer these questions, we propose a randomized controlled trial comparing a sexual risk

reduction intervention that includes an alcohol risk reduction component and a marijuana risk reduction component (SRRI+ETOH+THC), to a sexual risk reduction intervention that includes only an alcohol risk reduction component (SRRI+ETOH), to a sexual risk reduction intervention that does not include substance use content (SRRI).

V. Experimental Design and Methods

The study is a between-subjects randomized controlled intervention with three conditions. Participants will be randomly assigned to receive a sexual risk reduction intervention (SRRI), a sexual risk reduction plus alcohol risk reduction intervention (SRRI+ETOH), or a sexual risk reduction intervention that includes *both* an alcohol risk and marijuana risk reduction component (SRRI+ETOH+THC). Adolescents will participate in groups of up to eight in a three-hour one-session intervention two weeks or less prior to their release from detention. All adolescents will complete pretest measures prior to the intervention, immediate posttest measures after the intervention, as well as behavioral follow-up measures three months, six months, nine months, and one year after release.

In addition to the main study, we are also conducting *focus groups*, in which we interview members of the target population with the goal of gathering information that will help us tailor our intervention to this specific population, and a *pilot study*, which will allow us to test the feasibility of the intervention and its acceptability to the population; it will also serve as a training exercise for our research staff.

i) Experimental Procedures (main study): We have used similar experimental procedures in a previous study (HRRC 07-295), and we find that the following components reliably take the time indicated in parentheses below.

1. Assent/Consent (.25 hours, completed at detention center)
2. Self-Report Measures and DNA and urine collection (1.5 hours, completed at detention center)
3. Group Health Intervention and Posttest Assessment (3 hours, completed at detention center)
4. Follow-up behavioral assessments [3, 6, and 9 months (.5 hours each), and 12 months (1 hour) following participation, completed at location convenient for participant].

(1) Assent/Consent. Our participants come from the Bernalillo County Juvenile Detention Center, a facility designed to provide a safe environment for incarcerated adolescents and to encourage youth from further incarceration. Research assistants will inform young people of the opportunity to be involved in the study, and go through a detailed informed consent process. Participants will also be asked to sign a release form allowing the BCJDC to provide us with their Chlamydia and Gonnorhea test results if they were tested for Chlamydia and Gonnorhea at intake. Parental consent will then be obtained by contacting a parent/guardian by telephone. After parent/guardian and adolescent consent have been obtained, adolescents will be scheduled for the baseline, self-repot measures.

(2) Self-Report Measures and DNA and urine collection.

The baseline/pretest self-report measures will consist of the following:

Demographics: Page 1—"Demographic Information"

- Demographics: A Demographics Questionnaire will be used to collect information on age, sex, SES, employment, education, and race/ethnicity. In addition, the participants will be asked with whom they currently live when not in detention (e.g., both parents, one parent, foster parent, legal guardian), and the nature of the crime for which they received detention.

Impulsive Sensation Seeking Scale: Page 3—"IMPss"

- The impulsive sensation seeking scale (IMPss) from the Zuckerman-Kuhlman Personality Questionnaire (Zuckerman, 2002) is nineteen questions long and asks the respondent to answer true or false according to their feelings regarding impulsive decision making. We include this measure to examine relationships between impulsivity and baseline condom use, as well as change in condom use as a result of the intervention.

Condom Benefits: Page 4-"Condom Benefits"

- A 7-item questionnaire was validated by Dr. Bryan in previous studies of criminally-involved adolescents (Bryan et al., 2004; 2005). It presents statements ascertaining attitudes toward condom use (i.e. "Condom use would be a good thing for me to do if I was sexually active"). Items also measure attitudes toward different risks regarding sex (i.e. "I think it is very important for me to prevent getting a sexually transmitted disease like herpes or AIDS.") and ascertain beliefs on the benefits of condoms in addressing these risks (i.e. "I think condoms are effective at keeping people from getting AIDS."). Participants may respond to each item by indicating "Disagree a lot," "Kind of disagree," "Kind of agree," or "Agree a lot."

Condom Attitudes: Page 5- "Condom Attitude Scale"

- This scale assesses adolescents' attitudes about condom use in areas of promiscuity, interpersonal affect, and safety. The scale is a modified version of Sacco's Condom Attitude Scale (Sacco, Levine, Reed, & Thompson, 1991) that was validated for use in adolescent population (St. Lawrence, Reitman, Jefferson, Alleyne, Brasfield, Shirley, 1994). In this scale, seven items tap general attitudes towards condom use (e.g. "Using condoms every time I have sex would be:") and response options range from 1=very bad to 7=very good. Affective attitudes about condom use are assessed with 23 items (e.g. "Condoms take away the pleasure of sex.")

Condom Use Self-Efficacy Scale: Page 6- "Condom Self Efficacy"

- The CUSES (Brafford & Beck, 1991; Brien et al., 1994) is a self-report questionnaire which elicits responses using a five-point Likert scale format, ranging from `strongly disagree' to `strongly agree'. Each of the responses is scored as follows: `strongly disagree' = 0, `disagree' = 1, `undecided' = 2, `agree' = 3 and `strongly agree' = 4. After reversing for negatively worded items, scores are summed. The possible range of scores is 0–112, with higher scores indicating greater condom use self-efficacy (Brafford and Beck, 1991). The Condom Use Self-Efficacy Scale was derived from several sources and consisted of various items describing an individual's feelings of confidence about being able to purchase and use condoms. Not all items were used, and some have been edited to include condom use while under the influence of alcohol or marijuana.

Condom Use Norms: Page 8- "Condom Use Norms"

- This 8-item questionnaire was validated by Dr. Bryan in previous studies of criminally-involved adolescents (Bryan et al., 2004; 2005). Items assess participants' perceptions of normative condom behavior (e.g. "Most of my friends think people should always use a condom when having sex with a new

person."). These items also include items regarding condom use while under the influence of alcohol or marijuana.

Condom Use Intentions: Page 9- "Condom Use Intentions"

- Intentions to use condoms in the future are measured with items addressing participants' likelihood to engage in behaviors with regards to condom purchase/use (e.g., How likely is it that you will buy or get condoms in the next three months?). Items are based on a pool developed by Dr. Bryan in past studies of criminally-involved adolescents (Bryan et al., 2004; 2005). Some questions ascertain the likelihood of certain sex or condom-related behaviors while under the influence of marijuana or alcohol (e.g., How likely is it that you will use a condom when you have been drinking alcohol?)

Developmental Timing: Page 12- "Developmental Timing"

- The Physical Development Scale was developed by Peterson et al. (1988) to assess adolescents point of development. We are including it to assess not only our participants' ages, but also their point in natural physiological development.

Sexual History: Page 13- "Sexual History"

- Our measures of sexual behavior and condom use are culled from various sources including the PI's previous work and our current NIAAA and NIDA studies with this population. Participants are first asked whether they have ever had sexual intercourse (yes/no). At this point, the automatic skipping pattern of the ACASI instrument will be initiated to direct participants to the appropriate set of questions. Participants who have never had sexual intercourse will be directed to the next section of the questionnaire. Sexually experienced adolescents will be directed to questions about their sexual history, such as how old they were the first time they had sexual intercourse, how many sexual partners they have had, and average frequency of intercourse (response options range from "once a month or less" to "almost every day"). To assess frequency of condom use and contraceptive use since becoming sexually active, participants will be asked how often they have used condoms and how often they have used contraception with response options ranging from "never" to "always". Participants will be asked whether they have ever had a sexually transmitted disease (yes/no) and whether they have ever been pregnant (if female) or gotten someone pregnant (if male).

  Concurrent with procedures in our previous NIAAA and NIDA studies, participants will be asked to estimate, over their lifetime, "How much of the time have you been using alcohol when you've had sexual intercourse?" and "How much of the time have you been using marijuana when you've had sexual intercourse?". Then, participants will be asked the same set of questions with reference to the past three months only. Response options for all four questions range from "Never" to "Always" on a five-point scale. The most informative of all our alcohol and sexual activity measures in the previous study will then be repeated here. For participants who have had sex at least once and have had alcohol and/or marijuana at least once, there will be an event analysis of two recent intercourse episodes. Participants will be asked to recall the most recent time they had sexual intercourse while under the influence of alcohol and/or marijuana, and the most recent time they had sexual intercourse without being under the influence of any substance. For the episode in which they were under the influence, they will be asked if they had been drinking alcohol, smoking marijuana, or both. For both episodes, they will be asked whether or not they and their partner used a condom or used any other form of birth control, and what the relationship status of their partner was (e.g., "someone I just met", "a casual sexual partner", or

"my boyfriend or girlfriend"). For the intercourse episode including alcohol and/or marijuana, participants will be asked how much alcohol they consumed (ranging from "none" to "more than 20 drinks") and how much alcohol their partner consumed (ranging from "none" to "more than 20 drinks"), how high they were (ranging from "did not feel high at all" to "felt really high"), and whether their partner had been smoking marijuana.

Negative Sexual Consequences: Page 19—"Negative Sexual Consequences"

- This measure was modeled off of the RAPI and RDPI, and was used in Dr. Bryan's previous NIDA-funded study. Participants are presented with a list of items detailing negative consequences that may arise from sex. They are asked to indicate how many times each item happened to them while they were having sex or because of their sexual behavior during the last year. Responses are 1=never, 2=almost never, 3=sometimes, 4=frequently, 5=every time you've had sex. Sample items are "Regretted having sex with someone later"; "Felt that your reputation had been damaged"; "Your relationship with your partner changed in a negative way".

Positive Sexual Consequences: Page 20—"Positive Sexual Consequences"

- This measure was developed by Erika Montanaro, a graduate student working with Dr. Bryan. Participants are presented with a list of items detailing positive consequences that may arise from sex. They are asked to indicate how many times each item happened to them while they were having sex or because of their sexual behavior during the last year. Responses are 1=never, 2=almost never, 3=sometimes, 4=frequently, 5=every time you've had sex. Sample items are "Had an orgasm"; "Fit in better with your peer group"; "Relationship with your partner improved or was enhanced".

Alcohol use: Page 21—"Alcohol Use"

- Alcohol use will be evaluated with a variation of the measure used by White and Labouvie (1989). First, adolescents will be asked if they have ever had an alcoholic drink (with instructions that define one alcoholic drink as "one beer, one glass of wine, or one serving of hard liquor either by itself or in a mixed drink"). Those (likely well over 90%) who answer that they have previously had alcohol before will be asked to rate: (1) their frequency of use in the last three months on a 9-point scale ranging from "never" to "every day", (2) their typical quantity of drinks in one sitting on a 10-point scale ranging from "no drinks" to "more than 20 drinks", and (3) their frequency of getting drunk when drinking in the past three months on a 5-point scale ranging from "never" to "always".

Alcohol Use Disorders Identification (AUDIT): Page 22-"Alcohol Dependence"

- Alcohol Dependence: The Alcohol Use Disorders Identification Test (AUDIT) is a self-report assessment of hazardous drinking. A review of the use of the AUDIT showed that it had good sensitivity and specificity to lifetime alcohol dependence and that the reliability of measurement is typically high (Allen, Litten, Fertig, & Babor, 1997).

Rutgers Alcohol Problem Index (RAPI): Page 23—"Alcohol Problems"

- Alcohol Problems: Consistent with previously approved procedures, we will utilize a measure of alcohol problems, the Rutgers Alcohol Problem Index (RAPI; White & Labouvie, 1989). The RAPI was developed to specifically evaluate the alcohol-related problems of adolescents. The RAPI has high internal consistency, with $\alpha = .92$ in a sample of adolescents from 12 to 21, and .93 in our recent sample of probated adolescents. The RAPI correlates moderately with measures of alcohol quantity and frequency (White & Labouvie, 1989) and does not include items relating to sexual behavior while under the influence of alcohol, making it ideal for the present study.

Substance Use: Page 25- "Substance Use History Questionnaire"

- This measure has been used in previous NIH funded studies at the University of New Mexico and the Mind Research Network. It assesses the use (i.e., incidence and frequency) of several substances apart from alcohol and marijuana, which are the main focus of this study. Participants are sequentially asked if they a) have used a specific substance (e.g., cocaine), b) how old they were when they first used the substance, c) how many years they have used the substance, and d) how often they have used the substance in the past three months.

Fagerström Test for Nicotine Dependence (FTND-R) and Cigarette Use: Page 27—First questions are "Cigarette Use", Second set is "FTND-R"

- First, participants will be asked a series of general questions about cigarette use; they will be asked whether they identify as a smoker, asked about their cigarette use in the past 3 months, the age they smoked their first cigarette, and how long they have been smoking. The Fagerström Test for Nicotine Dependence will also be administered. This is a standard instrument for assessing the intensity of physical addiction to nicotine. (Heatherton TF, Kozlowski LT, Frecker RC, Fagerström KO. 1991), and asks questions such as "How soon after you wake up do you smoke your first cigarette?" and "How many cigarettes per day do you smoke?"

Marijuana Use: Page 29-"Marijuana Use"

- Marijuana Use: Participants will be asked if they have ever smoked marijuana. Those who answer yes will then begin a series of questions which ask: the age at which they smoked marijuana for the first time and how often they smoke marijuana (8-point scale where response options include occasionally, once a month, 2-3 times a month, 4-5 times a month, once a week, 2-3 times a week, 4-5 times a week, or every day).

Marijuana-Related Problems - Modeled after the Rutgers Alcohol Problem Index Marijuana (MJ-RAPI): Page 30—"Marijuana Problems"

- Marijuana Problems: We will use an adaptation of the RAPI to assess marijuana problems (RDPI; e.g., Johnson & White, 1995). The items of the RDPI parallel those of the RAPI, but ask about problems specific to marijuana use. This scale has been shown to have good reliability ($\alpha = .83$) as well.

Marijuana Dependence Scale (MDS): Page 32—"Marijuana Dependence Scale"

- Marijuana Dependence: The Marijuana Dependence Scale (MDS; e.g., Stephens, Roffman, & Curtin, 2000) is based on DSM IV criteria that were converted to a paper and pencil measure. Individuals respond 'yes' or 'no' to each dependence item (e.g., "When I smoked marijuana, I often smoked more or for longer periods of time than I intended"). The items are then summed to

form the scale. The internal consistency of the MDS has been good in our current NIDA study (α = .76).

Revised Sociosexuality Orientation Inventory: Page 33—"SOI-R"

- The SOI-R is a revision of the original measure developed by Simpson and Gangestad (1991). It measures three components of sex outside the context of a committed relationship: behaviors (e.g., With how many different partners have you had sexual intercourse on one and only one occasion?), attitudes (e.g., Sex without love is OK), and desires (e.g., How often do you have fantasies about having sex with someone with whom you do not have a committed relationship). Penke and Asendorpf (2008) report that each three-item factor has acceptable internal consistency.

Penn State Worry Questionnaire: Page 34—"Penn State Worry Questionnaire"

- The Penn State Worry Questionnaire (PSWQ) (Meyer, Miller, Metzger, & Borkovec, 1990) is a measure of worry phenomena that will be administered to participants. It presents 16 statements regarding worrying (e.g., If I do not have enough time to do everything, I do not worry about it; My worries overwhelm me; I do not tend to worry about things) and instructs participants to rate each statement on a scale of 1 ("not at all typical of me") to 5 ("very typical of me").

The Early Life Stress Questionnaire (ELSQ): Page 36—"Early Life Stress"

- The Early Life Stress Questionnaire (ELSQ) is a self-report questionnaire that measures the occurrence of potential Adverse Child Events. The ELSQ was developed for use in an international cohort (McFarlane et al 2005; Paul et al., 2005), and is based on the Child Abuse and Trauma Scale, which has been shown to have strong internal consistency, test-retest reliability, and validity, as it correlates with adult outcome and psychopathology (Sanders 1995)and is based on the Child Abuse and Trauma Scale (Sanders 1995); which has strong internal consistency, test-retest reliability, and validity, as it correlates with adult outcome and psychopathology. The ELSQ consists of 20 ACEs shown to be either traumatic or extremely stressful in past studies (De Bellis 2001; Harrison et al 1997; McGee et al 1995; Sanders and Becker-Lausen 1995) Participants endorsed whether specific ACEs had occurred during their lifetime and if so, at what age. These self-reported ACEs have been strongly correlated with agency estimates of childhood trauma (McGee et al 1995), including sexual and physical abuse, traumatizing accidents, natural disasters and sustained domestic conflict.

Child Behavior Checklist (CBCL): Page 38—"CBCL"

- The Child Behavior Checklist (CBCL) (Achenbach, 1991) was designed to assess behavioral problems and social competencies of children. Participants are instructed to read statements describing people (e.g., I argue a lot, I fail to finish things that I start, I have trouble concentrating or paying attention) and indicate how true each statement is of them on a 3-point scale ranging from "never true" to "very true or often true".

Time Line Follow Back (TLFB):

- TLFB is an interview assessment that includes a calendar to help people provide retrospective estimates of their daily sexual behavior and daily alcohol, cigarette, and marijuana use. Several memory aids are used to help participants recall their behavior including the use of key dates

(e.g., holidays), black and white days (e.g., lengthy periods of time when they abstained), discrete events (e.g., arrests, hospitalizations), use boundaries (e.g., greatest and least amount used during reporting period), and exaggeration techniques (e.g., If a participants says he/she drinks "a lot" the interviewer might ask if a lot means 2 drinks or 30 drinks). Two times frames will be asked about. First, participants will answer yes/no dichotomous questions about their behavior over the past 6 months. For example, "In the past six months, have you had an alcohol drink?" Second, participants will answer questions about their behavior during the past 30 days prior to incarceration. These questions are more detailed. "When you drank, how many drinks did you have at one time?" TLFB will be conducted at baseline, 3, 6, 9, and 12 months.

At this time, participants will provide 5mL saliva to be typed for DRD4 variant.

Participants will also provide a urine sample if they were not tested for Chlamydia and Gonorrhea at intake. Participants take a bathroom break between the baseline assessment and the intervention, and the urine sample will be collected at that time. Urine will be collected in a plastic collection cup, which will be labeled with the participant ID number and transported to TriCore Reference Laboratories, which conduct tests such as these for UNM researchers. Samples will then be assayed for *Chlamydia Trachomatis* and *Neisseria Gonorrhoeae* using polymerase chain reaction (PCR) analyses. TriCore staff will inform our research staff which, if any, participant ID numbers had positive tests, and which bacteria they tested positive for. Our staff will contact the participant who tested positive and arrange a meeting to provide a single dose treatment for the infection.

The three month follow-up will include the following measures included in the baseline:

Demographics (Page 1)
Condom Use Intentions (Page 3)
Sexual History (Page 8)
Alcohol Use (Page 15)
Alcohol Dependence (Page 16)
Alcohol Problems (Page 17)
Substance Use History (Page 19)
Fagerström Test for Nicotine Dependence (FTND-R) and Cigarette Use (Page 20)
Marijuana Use (Page 21)
Marijuana Problems (Page 22)
Marijuana Dependence (Page 25)

The three month follow-up will also include measures of experience with and attitudes toward gangs and other social groups.

Collective Self Esteem Scale (Page 26)

- The collective self esteem scale was developed by Luhtanen and Crocker (1992) as a means for evaluating individuals' attitudes toward their social identity. We have modified the measure to address a particularly important (and socially problematic) group among this high-risk population: gangs.

The six month follow-up will include the following measures included in the baseline:

Demographics (Page 1)
Condom Use Intentions (Page 3)
Sexual History (Page 8)
Alcohol Use (Page 14)
Alcohol Dependence (Page 15)
Alcohol Problems (Page 16)
Substance Use History (Page 18)
Fagerström Test for Nicotine Dependence (FTND-R) and Cigarette Use (Page 19)
Marijuana Use (Page 21)
Marijuana Problems (Page 22)
Marijuana Dependence (Page 25)

The six month follow-up will also include three measures that were not on the baseline or three month follow up. These measures include:

Substance Abuse Intentions (developed by investigators) (Page 26)

- The major goal of the project is to compare the effectiveness of the three intervention conditions on decreasing substance abuse. However, several of our study participants are housed in detention or treatment facilities, and thus do not engage in any substance use due to their surroundings. We have included these items on *intentions* to use substances to measure if intentions, independent of behavior, vary across intervention conditions.

Marijuana Motives Scale (Simons, Correia, Carey, and Borsari, 1998) (Page 28)

- The marijuana motives scale was developed to measure the factors motivating marijuana use and abuse. It is typically used in adult populations; we are using it to investigate the motivating factors behind marijuana abuse in a younger, high risk population.

State-Trait Anger Expression Inventory-2 (Spielberger et al., 1999) (Page 32)

- Many members of the study population come from difficult backgrounds and enter the juvenile justice system after emotionally motivated events (e.g., fighting). We are including these items to examine how expressions of anger and frustration relate to risky behavior and responses to the intervention.

The six month follow-up will include the following measures included in the baseline:

Demographics (Page 1)
Condom Use Intentions (Page 3)
Sexual History (Page 8)
Alcohol Use (Page 14)
Alcohol Dependence (Page 15)

Alcohol Problems (Page 16)
Substance Use History (Page 18)
Fagerström Test for Nicotine Dependence (FTND-R) and Cigarette Use (Page 19)
Marijuana Use (Page 21)
Marijuana Problems (Page 22)
Marijuana Dependence (Page 25)

The nine month follow-up will also include one measure that was not included in the baseline assessment or three or six month follow-ups. This measure is:

Revised Shorteneed Self-regulation Questionnaire (SSRQ; Neal & Carey, 2005) (Page 32)

- The *Short Self-Regulation Questionnaire* (SSRQ; Carey et al., 2004) is a 31-item questionnaire, based on the Self-Regulation Questionnaire (SRQ; Brown, Miller, & Lawendowski, 1998) that was designed to assess self-regulation capacity across the seven processes of self-regulation. This is a 21-item questionnaire based off the above scales. A major component of the study involves understanding the role of impulsive behavior in risky decision-making. This instrument helps measure self-regulation, which presumably underlies impulsive behavior.

The twelve month follow-up will include the following measures included in previous questionnaires:

Demographics (Page 2)
Condom Benefits (Page 4)
Condom Attitudes (Page 5)
Condom Self-Efficacy (Page 9)
Condom Use Norms (Page 11)
Condom Use Intentions (Page 13)
Sexual History (Page 16)
Negative Sexual Consequences (Page 22)
Positive Sexual Consequences (Page 24)
Alcohol Use (Page 26)
Alcohol Dependence (Page 27)
Alcohol Problems (Page 29)
Substance Use History (Page 31)
Fagerström Test for Nicotine Dependence (FTND-R) and Cigarette Use (Page 33)
Marijuana Use (Page 38)
Marijuana Problems (Page 39)
Marijuana Dependence (Page 43)
SOI-R (Page 44)
Substance Abuse Intentions (Page 46)
State-Trait Anger Expression Inventory-2 (Page 49)
Revised Self-Regulation Questionnaire (Page 50)

(3) Group Health Intervention and Posttest Assessments.

After completion of the baseline assessment, participants will be scheduled for their group intervention. In each condition, participants will meet in a group in a visiting room within the detention facility. There will be a masters-level graduate research assistant trained to conduct the intervention and specifically trained in MET. Co-I Dr. Feldstein Ewing will conduct all MI/MET trainings, will supervise the therapists on the project, and will conduct ongoing meetings with them to ensure consistency and quality control. Another member of the research staff will be available during the intervention to assist in matters such as setting up computers and conducting the process evaluation. A detention staff member will also be on hand outside of the classroom for security and safety. Interventions will be audio recorded using a digital recorder. Audio recording sessions enables us to evaluate the integrity of the MI therapy session. Specifically, Co-I Dr. Feldstein Ewing will randomly listen to session tapes to provide ongoing supervision of the therapists and the intervention. In addition, audio recorded sessions enable evaluation of the intervention fidelity using the Motivational Interviewing Treatment Integrity (MITI) Coding System, a fidelity approach employed in previous studies by Dr. Feldstein Ewing. The MITI has gained support as a solid measure of treatment fidelity for MI. Random 10-minute segments will be collected from each recording of the MI session and scored using MITI. Inter-rater reliability will be evaluated through the double coding of 25% of the recorded sessions. Virtually identical procedures have been used in Dr. Feldstein Ewing's other ongoing intervention projects (HRRC #'s 09-366, 09-226, 09-323).

Participants will then take part in the three-hour intervention program depending on which condition they were randomly assigned to: 1) sexual risk reduction (SRRI), 2) SRRI with alcohol-specific risk reduction content (SRRI + ETOH), or 3) SRRI with both alcohol and marijuana-specific risk reduction content (SRRI + ETOH + THC). The sexual risk reduction intervention is based on the completed NIAAA-funded intervention study, as well as on previously successful HIV/STD risk reduction interventions conducted with young adults (Bryan et al., 1996; Fisher et al., 2002; St. Lawrence et al., 1999), and is divided into 5 sections. Section I is 10 minutes long and addresses HIV/STD transmission, defines relevant terms, enumerates behaviors that place people at risk for HIV/STDs, and identifies local HIV/STD resources.

Section II is 40 minutes long and focuses on condom use self-efficacy (e.g., confidence obtaining, carrying, and using condoms), as well as the ability to effectively communicate safer sex wishes to a partner. Participants will first complete the Game of Choices on their laptop. In the Game, participants make a series of choices: whether to go to a party or stay home with friends, whether to carry condoms, whether to have sex, whether to talk to their partner about condoms, and whether to use condoms. The substance use interventions will also include choices to drink or smoke marijuana. The next exercise is a brief discussion about how one goes about obtaining condoms and how to properly carry and store them. The third exercise is a discussion of how participants might go about talking to their partner about using condoms. The fourth exercise is the condom familiarization activity. This activity provides participants with a hands-on demonstration of how to properly use a condom, and then the opportunity to practice this skill themselves using a wooden penis model.

Section III addresses the many possible outcomes sexual behavior may have and different strategies people can take in order to prevent negative outcomes. Section III also targets negative attitudes and norms about condom use and condom users by emphasizing the positive aspects and acceptability of each. Section III is 25 minutes long. The first part of this section involves watching a video that demonstrates a four young couples' experiences with sexual decisions. There will be several pauses

during this short video to stimulate discussion about what participants think the couples should do, will do, and why they should or will do it.

Section IV will consist of the appropriate MET component: sexual risk, alcohol-related risk sexual risk, or alcohol- and marijuana-related sexual risk. This section is 60 minutes long and is structured in a group MET (GMET) style based on the MET approach originally created by Miller and colleagues (i.e., Miller, Zweben, DiClemente, & Rychtarik, 1999). As with other MET approaches, this GMET addresses adolescents' awareness and ambivalence about their level of risky sexual behavior, alcohol, or alcohol and marijuana consumption, the potential consequences of these behaviors, including these behaviors' effects on decision-making. In these discussions, through MET approaches such as using open questions, affirmations, reflections, and summary statements, group leaders will be actively eliciting participants' change talk about these risk behaviors, including statements regarding their desire, ability, reasons, need for change (Miller & Rollnick, 2002). Strategies to reduce risk behavior, and their potential efficacy, will be elicited from the participants. Approaching these discussions with the fundamental MET principals of Rolling with Resistance, Expressing Empathy, Developing Discrepancy, and Supporting Self Efficacy (REDS; Miller et al., 1999; Miller & Rollnick, 2002), the GMET utilizes a set organization based on the following elements: 1) based on pre-test data, the group will receive normative data feedback based on that specific *group's* level of risky behavior. The group leader will open a discussion with the group by providing the group with objective, non-judgmental feedback about their level of risky behavior. 2) Next, the group leader will support the participants' autonomy, but emphasizing those participants have a choice in the decision to make positive changes in their risk behavior. 3) The group leader will present material in a genuine and accurately empathic manner. 4) Utilizing the Sexual Risk, Alcohol Risk, or Alcohol and Marijuana Risk video, the group leader will query potential alternatives to risk behaviors addressed in the video relevant to that behavior. 5) The videos will be paused in several places to elicit participants' thoughts about what is going to happen and why, and about what the friends should do and why. 6) Following the video, through a collaborative approach between the participants and the group leader, the group leader will elicit potential alternatives to risk behavior that might be effective for the participants to reduce risk in their own lives.

Section V addresses consequences of sexual behavior decisions and long-term safer sex behavioral goals by focusing on condom use intentions. This section is 10 minutes long and focuses on being oriented towards the future and being planful in one's intentions to reduce their risk. First, participants will play the "Wheel of Future" game which contains a number of possible behavioral outcomes. Participants will be asked to write down a goal they hope to obtain in the next 3 years, and will then spin the wheel. Possible wheel options range from "You decide to have unprotected sex and are now HIV+," to "You decide to always use a condom when you have sex." Participants will then discuss how the decision described on their spin will affect their ability to achieve their goal (e.g., if an adolescents' goal is to enter the military, how will being HIV+ influence that goal?) Finally, participants will write down a specific safer sex goal they hope to achieve in the next 3 months.

After the intervention, participants will also complete a short immediate posttest. At the end of the posttest questionnaire, participants will be asked to write down on a separate piece of paper (i.e., not on the computer) their contact information, where they plan to live upon release, phone numbers and email addresses (if any), and names and contact information of multiple people who will always know how to reach them. Participants will be reminded that we will not tell contacts any specifics of the research, but any person they list will potentially find out about their participation in "a research study" and thus could violate the terms of the Certificate of Confidentiality obtained for the research. Participants will also indicate their date of birth and ethnicity for tracking in a database maintained by the detention center, which will aid our abilities to determine participants' current locations and enhance retention

rates. Adolescents are often mobile and might move between parents, switch guardians, or be incarcerated in a different facility. Using the database is the best chance we have at contacting participants when the information they provide us is no longer current.

Please note that the research data (contained on the computer) and the identifying information (contact information sheets which are then entered into a totally separate and password-protected tracking database) will at all times be maintained separate and secure. Thus, no identifying information will EVER be connected to participants' data and detention center staff will not have access to any data. Participants will be paid $20 for participating in the intervention. As previously described, money orders made out to each participant will be left with the detention center secretary until the participant is released, at which time they may pick it up with their personal property.

In the event of a positive STD test, we will provide medication to treat the infection. We will provide one gram Azithromycin and/or 400 mg Cefixime, both of which are single dose, directly observed therapy (DOT) treatments commonly used for these infections. If the participant is still in the BCJDC, we will provide the medication to the nursing clinic housed within the facility, and the clinicians in the facility will administer the single dose treatment and monitor the participant for any adverse reactions to the medication. If the participant has been released from the BCJDC, he or she will schedule a time and location to meet the participant and deliver treatment. Our staff will meet the participant and provide the DOT treatment and monitor the participant for negative reactions for thirty minutes after the participant has taken the medication.

(4) Follow-up behavioral assessments.

The brief follow-up questionnaires administered at 3, 6, and 9 months post-intervention will contain only the behavioral measures related to alcohol and marijuana use, alcohol and marijuana problems, sexual activity during the previous three months. The extensive follow-up questionnaire administered at 12 months will contain the same behavioral items as the follow-up assessments in addition to many of the measures from the pretest questionnaire. This will allow us to determine whether changes in model constructs including attitudes towards condom use, self-efficacy for condom use, and intentions to use condoms, have maintained postintervention levels or whether effects have decayed over time. Additionally, TLFB will be administered at 3, 6, 9 and 12 month follow-ups only.

In order to decrease our attrition rate, we will send postcards to participants 1 and 2 months after the intervention, and after each proceeding follow-up assessment until they have completed the study (example attached). This is done to remain in contact with the participants and to encourage them to notify us of any changes in their contact information. Participants will be called 2-weeks before each follow-up assessment as reminder that they will soon have an assessment to complete. Participants will also receive a bracelet after the baseline that has the name of the study, "Project MARS" and the study's toll-free number. Finally, after each assessment period, participants will receive a laminated card, that will easily fit into a purse or wallet, with a reminder to contact the study staff around a certain date to set up their next survey. These will have the date that they should call us, reminds them they will get $40 for the survey (or $50 for the 12-month follow-up), and will have a contact person and a number for contacting Project MARS.

i) Experimental Procedures (focus groups): Focus group procedures include two segments:

1. Assent/Consent (ten minutes, completed at detention center)
2. Focus group interview

(1) Assent/Consent. Research assistants will inform young people in the detention center of the opportunity to be involved in the focus, and go through a detailed informed consent process. This process is shorter than that for the main study given the shorter length of duration and less involved procedures of the focus groups. Parental consent will then be obtained by contacting a parent/guardian by telephone. After parent/guardian and adolescent consent have been obtained, adolescents will be scheduled for a focus group session.

(2) Focus Group Interview. On the day of the focus group, participants will be in a room within the detention center. Focus groups will be stratified by gender, such that none of the groups will include both boys and girls. This is a practical necessity instituted by the detention facility involved, but is also commensurate with teaching and discussing sensitive sexual information with adolescents. Also present will be the focus group leader (a Masters level UNM psychology graduate student extensively trained in the delivery of focus group material) and a technical assistant (a Research Assistant on the staff of the project) to help with the audio recording equipment and distribute focus group materials to participants.

Focus group questions are divided into several sections: marijuana use; alcohol use; sexual behavior, condom use, and sexually transmitted infections; marijuana use and sexual behavior; alcohol use and sexual behavior; abstinence and condom use; feedback on previously used videos; and advice for longitudinal data collection.

Feedback will be recorded on an audio cassette tape, and will later be transcribed and incorporated into our design of the intervention content for the main study.

Participants will be reminded why they have been brought together, and will be reminded again that their participation is totally voluntary. After the focus group, participants will receive monetary compensation of $30 for their time and effort.

i) Experimental Procedures (pilot study): Pilot study procedures include two segments:

1. Assent/Consent (.25 hours, completed at detention center)
2. Self-Report Measures (1.5 hours, completed at detention center)
3. Group Health Intervention (3 hours, completed at detention center)

Procedures for the pilot study are identical to those described for the intervention study above with two exceptions. 1) No follow-up assessments will be conducted. Participants will only complete a pretest questionnaire, participate in an intervention, and after the intervention, give feedback about the intervention. 2) No saliva samples will be collected.

As with other aspects of this project, we will recruit participants from the detention and will require participant assent and parental consent before anyone may participate in the pilot study. All risks and benefits will be explained in detail and all assent/consent procedures previously described will be followed. Separate consent and assent forms for the pilot study describe in detail what participants will be asked to do. After assent and parental consent are obtained, participants will be scheduled to complete the pretest questionnaire which will take approximately 1 hour. Then, participants will be scheduled for the intervention. The intervention and feedback session will take about 3 hours. Participants will receive $30 for their time.

The pretest questionnaire will be identical to that described above in the “Pretest Questionnaire” section. The feedback session following the intervention will consist of a short group discussion in which the researcher will ask participants to describe what they liked and disliked about the intervention. As with the focus group, these discussions will be recorded so the experimenters can refer back to the discussion and not miss what has been said.

ii) Data Management. All data collection during the intervention phase of the study will take place via Audio Computer-Assisted Self-Interviewing (ACASI) technology on individual laptop computers. ACASI has proven to be a reliable way to obtain survey data assessing risk behaviors (Williams et al., 2000). ACASI technology allows for survey questions to be displayed on a laptop computer screen and for questions to be digitally recorded, allowing respondents to hear spoken questions over headphones while they read the question on the computer screen. One of the main benefits of using ACASI technology is that it has been shown to increase levels of self-reporting, especially with regard to high-risk behaviors (Wight et al., 2000; Gribble, Miller, Rogers, & Turner, 1999; Turner et al., 1998). Our experience in our prior NIAAA funded projects with adjudicated adolescents and that of others (e.g., Lessler & Holt, 1987), has been that for high-risk adolescents both literacy and the ability to negotiate even very simple skip patterns are problematic. ACASI technology is uniquely accessible to those who have low levels of literacy. ACASI technology further eliminates errors of contingent questioning, as skip patterns are automatically initiated based on a respondent's answers.

All electronic data will be kept on a password-protected computer server and any physical information (e.g., consent forms) will be stored in a locked filing cabinet in Dr. Bryan's research laboratory. Only those directly involved in this project will have access to this information. All personal indicators will be destroyed after the 12-month follow-up has been completed.

Data Analyses and Interpretation. Analyses will be conducted primarily using SAS Version 9.1 and Mplus Version 5 (Muthén & Muthén, 1998-2008). Both programs include capabilities to test models with categorical outcomes, missing data, and to account for a design that occurs in a multilevel framework (Bryan, Schmiege, & Broaddus, 2007). Estimation of the model of intentions. Individual confirmatory factor analyses (CFA) and a multicomponent CFA will be conducted on model constructs to confirm their convergent and discriminant validity. The structural model of intentions will then be estimated in the entire pretest data set (Loehlin, 1992). Pretest equivalence. To test the success of random assignment, the pretest equivalence of conditions across demographics, sexual experience, and all model constructs will be assessed via t-tests on continuous items and $\chi 2$ tests of categorical items from the pretest. We will use the Bonferroni approach (Keppel, 1991) to correct for alpha inflation with a familywise alpha of .05. Specific Aim 1 - Intervention Effects on Behavior at Follow-up. Analyses will be conducted in a multilevel framework to account for clustering within groups (Schmiege et al., 2008). SAS Proc Mixed will be utilized for continuous outcomes and SAS Proc GENMOD will be utilized for categorical outcomes to study intervention impact on behavioral outcomes at the follow-up occasions (HYPOTHESES 1, 2, 3, & 4). Six classes of dependent variables will be assessed: 1) Condom use behavior, both over the previous three months and at most recent intercourse, 2) Alcohol use and alcohol problems, 3) Use of alcohol in conjunction with sexual activity, 4) Marijuana use and marijuana problems, 5) Use of marijuana in conjunction with sexual activity, and 6) STI incidence. Condom use behavior will be assessed at each follow-up occasion using both continuous items, (e.g., "How often have you used condoms in the past three months") and dichotomous items (e.g., "Did you use a condom the last time you had intercourse). STI incidence will be assessed with a positive or negative test at the 12-month follow-up. A secondary sexual behavior outcome will be the sexual risk problems index (CORSPI). The overall condition effect on condom use behavior, STI incidence, and sexual risk problems will first be examined. Provided there is a significant difference between conditions from this omnibus test, planned contrasts will be conducted to compare each of the three conditions to one another

to better understand this difference (HYPOTHESIS 1). Frequency of alcohol use and level of alcohol problems as assessed by the RAPI will serve as continuous alcohol use and alcohol problem outcomes at each of the follow-up occasions. The main comparison here will be an analysis of whether the SRRI+ETOH and the SRRI+ETOH+THC interventions elicited greater reductions in alcohol use and problems than the SRRI only intervention (HYPOTHESIS 2). Thus, intervention (coded to reflect the planned comparison described, see Judd & McClelland, 1989) will be entered into the multilevel models predicting alcohol use and alcohol problems at each follow-up. Finally, alcohol use during sexual activity will be assessed using both continuous (e.g., "In the past three months, how much have you been using alcohol when you had sexual intercourse?") and categorical (e.g., "The last time you had sexual intercourse, were you drinking alcohol?") measures. Again, the main outcome of interest will be the comparison of the SRRI+ETOH and SRRI+ETOH+THC condition to the SRRI-only condition. Frequency of marijuana use and level of marijuana problems as assessed by the RDPI will serve as continuous marijuana use and marijuana problem outcomes at each of the follow-up occasions. The main comparison here will be an analysis of whether the SRRI+ETOH+THC intervention elicited greater reductions in marijuana use and problems than either of the other two interventions (HYPOTHESIS 3). Intervention condition, coded to reflect the planned comparison described (see Judd & McClelland, 1989) will be entered into regression equations predicting marijuana use and marijuana problems at each follow-up. Finally, marijuana use during sexual activity will be assessed using both continuous (e.g., "In the past three months, how much have you been using marijuana when you had sexual intercourse?") and categorical (e.g., "The last time you had sexual intercourse, were you smoking marijuana?") measures. Specific Aim 2 - Mediational analyses. Mediational analyses based on path analyses will be used to examine the mechanisms by which the program has had its impact upon behavioral outcomes (HYPOTHESIS 4) (Baron & Kenny, 1986; Bryan et al., 2007; MacKinnon & Dwyer, 1993; West et al., 1993). Mediational analyses will allow us to determine whether changes in model variables (e.g., attitudes, self-efficacy) led to reductions in risk behavior (e.g., use of alcohol/marijuana during intercourse, unprotected intercourse). Since we must have both behavioral follow-up data and model variables to perform these analyses, the mediational analyses will be conducted utilizing the relevant the behavioral assessments at 3 months post-intervention, as this is when we expect the strongest effects of the intervention minimally diluted by the passage of time and other historical factors. The first step in conducting such analyses is to examine the effect of the intervention on model constructs proximal to condom use behavior. Assuming pretest equivalence on all measures, posttest intervention outcomes will be assessed by comparing the posttest values for model constructs in the SRRI, SRRI+ETOH, and SRRI+ETOH,+THC groups. Using SAS Proc Mixed, we will first examine the overall difference between the three intervention conditions on each individual outcome. Provided there is an omnibus difference between groups, planned contrasts will examine specific differences among the three conditions. There are at least three important mediational analyses to be conducted, in which any variable where there was a significant difference among conditions will be included. First, a mediational analysis will be conducted to determine whether the pattern of greatest condom use in the most comprehensive intervention (i.e., SRRI+TOH+THC > SRRI+ETOH > SRRI) was mediated through changes on model constructs. Second, a mediational analysis will be conducted to determine whether greater condom use behavior among SRRI+ETOH and SRRI+ETOH+THC participants than among SRRI participants is mediated by the effect of the intervention on all substance use during sexual encounters. Finally, a mediational analysis will be conducted to determine whether greater condom use among SRRI+ETOH+THC participants relative to the two other conditions was mediated by the effect of the intervention on marijuana use during sexual encounters. In order to test these models, two binary-coded, orthogonal contrast variables for treatment condition will serve as the

exogenous variable in a path analytic model. The specific contrasts will depend on the mediational question at hand. For example, a contrast that allows for comparison of the SRRI versus the two combined interventions will allow for examination of the impact of substance use content overall and for examination of the two programs that incorporated an alcohol risk reduction component to one without such a component. A second contrast that is orthogonal to the first one would be to compare just the SRRI+ETOH condition to the SRRI+ETOH+THC condition to determine the unique effect of incorporating a marijuana risk reduction component. For a putative mediator to be included in the model, the intervention must have affected the mediator (Judd & Kenny, 1981). For simplicity, assume that intervention changes occurred primarily on the attitudes, norms, and self-efficacy model variables. The model is then estimated in Mplus, and both the fit of the model and the significance of the path coefficients is examined. If paths from the intervention condition contrasts to the mediators are significant, and paths from the mediators to the outcomes are significant, then mediation is suggested. Importantly, bootstrap methods will be used to test the significance of, and confidence limits around, the mediated effect. Use of bootstrapping has been recommended due to greater power (i.e., relative to the Sobel, 1982 multivariate delta method) for detecting the mediated effect (MacKinnon, Lockwood, & Williams, 2004; Shrout & Bolger, 2002) and is practical because it is easily implemented in Mplus. Mediational analyses of this type are recommended by West and Aiken (1997) for the deconstruction and explanation of program effects in multi-component interventions, and have been utilized successfully in an evaluation of a condom promotion intervention by the PI (Bryan et al., 1996) and in analyses of the ongoing intervention with adolescents in detention (Schmiege et al., 2008). Specific Aim 3 – Moderation of Intervention Effects by Substance Use. To determine whether the two combined interventions were differentially effective for adolescents with high versus low alcohol and marijuana problems at baseline, a series of moderational analyses will be undertaken. To test HYPOTHESIS 5, a model will be estimated wherein experimental condition (coded to compare the SRRI to a combination of the SRRI+ETOH and SRRI+ETOH+THC conditions) and the centered continuous score on the RAPI (see Aiken & West, 1991) are included as main effects, and the Condition X RAPI multiplicative term is included as the interaction between intervention and alcohol problems. We hypothesize that these analyses will show a substantial increase in intervention success favoring the two combined interventions for those with high alcohol problems at baseline, while for those with low alcohol problems, we anticipate smaller differences between the combined and SRRI interventions. Similarly, to test HYPOTHESIS 6, the effect of an interaction between marijuana problem at baseline with a contrast comparing the SRRI+ETOH+THC program to a combination of the other two programs on condom use and marijuana use during sexual activity will be tested and interpreted. Differential attrition analyses. Attrition analyses will be conducted after each follow-up data collection effort to provide assurance that differential attrition by condition has not occurred between pretest and subsequent measurements. A series of 3 X 2 ANOVAs of Condition (SRRI, SRRI+ETOH, SRRI+ETOH+THC) X Retention (retained, not retained) (Jurs & Glass, 1971) will be conducted on continuous pretest measures. Significant Condition X Retention interactions identify measured variables on which differential attrition may have occurred. The logit model analog (Agresti, 1990, pp. 91-93) of the same procedure will be applied to categorical pretest measures to test for differential attrition on variables such as gender and ethnicity. We will conduct these analyses to assure that differential attrition by condition does not account for any of the effects of our intervention. These analyses were used successfully in Bryan et al. (1996) and Schmiege et al. (2008). Specific Aim 4 -- Moderation of Intervention Effects by Genetic Factors. To determine whether the two combined interventions were differentially effective for adolescents with DRD4s and DRD4l, moderational analyses identical to those outlined under Specific Aim 3 in this section will be conducted. Briefly, to test Hypothesis 7, a model will be estimated wherein

experimental condition and DRD4 (DRD4s vs. DRD4l) will be included as main effects, and the Condition X DRD4 multiplicative term is included as the interaction term between intervention and genetic factors. We hypothesize that intervention effects will be stronger DRD4S individuals and weaker for DRD4L individuals. Exploratory Aim – Moderation of Intervention Effects by Race, Gender, and Intervention Fidelity. The nature of the design and the characteristics of the sample present the opportunity for a number of secondary analyses. First, the issue of gender differences in sexual risk behavior among high-risk adolescents is grossly understudied, often because of the gender imbalance in criminal justice samples. Our data show evidence of several main effects of gender on study variables (e.g., attitudes, norms, intentions, and condom use behavior), and there is initial evidence for differential program effects as a function of gender on the selfesteem of participants. Unfortunately, even though effect sizes involving gender tend to be moderate, it's difficult from a power perspective to test these questions in our completed study because only 18% of the sample was female. Special efforts are being undertaken in the proposed study in order to ensure that at least 30% of participants are female, and thus gender differences in model constructs, behavior, reaction to the intervention and sexual risk behavior over the course of the follow-up will be examined. Another important characteristic of the sample will be its diversity in terms of ethnicity. Initial analyses of ethnicity (coded "White", "Hispanic", and "Other") as a moderator of the NIAAA-funded intervention show that the combined program was more effective in influencing intentions to use condoms (both generally and specific to alcohol contexts) for non-white participants than for white participants. Furthermore, differences between all three conditions on intentions were observed for non-white participants, but not for white participants. In the proposed project, we will again be able to examine moderational questions related to ethnicity, though the exact race/ethnicity questions are different in New Mexico, a minority-majority state. Based on the demographics of the detention center youth, the sample is expected to be over 60% Hispanic and 20% Caucasian, still allowing for comparisons across "Hispanic", "White", and "Other" categories. Importantly, the studies that show the strongest relationships between marijuana and sexual risk (those of Kingree and colleagues) are conducted almost exclusively with African American adolescents, so it is important for us to compare this relationship by race/ethnicity in our sample, which will be predominantly Hispanic, to see whether the relationship is consistent or differs across race. Finally, the extensive intervention fidelity data being collected in this project will allow us to examine the moderation of intervention effectiveness based on characteristics of intervention fidelity. Relationship between alcohol and risky sexual behavior. Consistent with all of our prior work, we will examine the relationship between substance use and risky sex at a number of levels of analysis. The level that shows the most promise among adolescents is assessment at the within-subjects episodic level. The use of two intercourse episodes per participant results in a comparison of dependent proportions. Differences in the proportion of condom use at an episode involving alcohol or marijuana versus the episode in which neither substance was used will be assessed at each follow-up assessment with a dependent proportions χ^2 statistic, for which the significance test is McNemar's test (Agresti, 1990). This same procedure was utilized in two studies in which within-subjects comparisons between intercourse episodes were utilized (Testa & Collins, 1997; Tubman & Langer, 1995), as well as in our previous NIAAA and ongoing NIDA studies. A secondary objective of the current work is to replicate the finding of our previous investigation of a significant episodic association between alcohol use and condom use and to further examine the little-studied episodic relationship between marijuana use and condom use. Given a statistically significant association between substance use and lack of condom use during intercourse, a number of additional analyses will be undertaken involving the influence of third variables (e.g., RAPI, RDPI, partner type) that may be involved in this relationship.

iii) Experimental drugs, devices, or procedures. No experimental drug, device, or medical procedure will be utilized.

iv) Biological Samples. We are collecting saliva for the purpose of analyzing DNA as a moderator of intervention effects on behavior. DNA will be identified only by a random subject ID number. The list linking subject ID numbers to identifying information is at all times maintained separate and secure from the DNA, and is in fact never housed in the same building. Once the study is complete (i.e., the final 12-month follow-up assessment is completed) all identifying information is destroyed and thereafter there will be no way to link the DNA with a subjects' name or other identifying information.

We are also collecting urine at baseline from participants who have not been tested for STIs in the detention facility, and we are collecting urine from all participants at the 12-month follow-up. We are collecting urine to test for *Chlamydia Trachomatis* and *Neisseria Gonorrhoeae*, two STIs common in this population. The same safeguards used for saliva specimens are used for urine specimens. The list linking subject ID numbers to identifying information is kept separately from urine samples at all times. The urine specimens are destroyed immediately after they are assayed for Chlamydia and Gonorrhea.

VI. Human Subjects

i) Describe characteristics (inclusion criteria) of subject population, including precautions to be taken with vulnerable populations (e.g. children, prisoners, mentally ill/disabled person).

Inclusion
Eligible adolescents must be in the participating detention facility, be between the ages of 14 and 18 years old, be English-speaking, have a remaining term in detention of no longer than one month, and must consent to be contacted again 3, 6, 9, and 12 months after release from detention. Each participant must have the fully informed consent of a parent or legal guardian, and must give their personal fully informed assent to participate.

Our goal is to recruit participants who will be in the detention center no longer than one month after the start of the study, however, we anticipate that some participants will be re-incarcerated following this period. All participants will remain eligible for follow-up assessments regardless of incarceration status.

Children as a vulnerable population
Children ages 14-17 will be included in this protocol (note 18 year olds are also included, and are defined as children by NIH, but are of the age of consent). The assessments to be performed in this protocol (such saliva collection, urine collection, behavioral intervention, and self-reported attitudes and beliefs) have been commonly performed and are accepted as routine in the medical and psychiatric and psychological communities. The probability and magnitude of harm or discomfort from this research is no greater than that which would be encountered in these communities. Therefore, this study does not expose children to any greater than minimal risk. Further, we go to great lengths to assure valid assent/consent procedures and to protect the confidentiality of minors involved in this work (see sections

on protection from risk below).

ii) Provide approximate number of subjects (both control and intervention groups). Intervention study participants will include 520 adolescents in detention in the state of New Mexico. There will also be 32 focus group participants and 16 pilot participants, for a total of 568 participants.

iii) Exclusion criteria.

There is no exclusion criteria for this study. All interested adolescents who meet the inclusion criteria, give their assent, and have parent/guardian consent will be eligible to participate.

iv) Describe recruitment methods.

Potential study participants will be made aware of the opportunity to participate in a project conducted by researchers at the University of New Mexico by members of the research team who will visit the recruitment location (i.e., the Bernalillo County Juvenile Detention Center) for this purpose. Adolescents (and later their parents) will be told that researchers at the University of New Mexico are developing programs meant to encourage healthy behavior among adolescents. They will also be informed that the researchers are interested in understanding who responds best to these interventions, and thus a number of individual difference measures including genetic information. These procedures will be fully explained to both participants and their parents. Participants will be told that they will be involved in programs that discuss sensitive topics such as sexual behavior, marijuana use, and alcohol use. The research staff member will be very explicit that participation is completely voluntary, and participation (or not) will in no way affect the young person's status in or treatment by the juvenile justice system. Recruitment will be conducted individually and without the immediate presence of juvenile justice staff in order to maintain the participants' confidentiality.

v) Assent and consent procedures.

Because children between the ages of 14 and 17 are not of age to give consent, we follow strict procedures for obtaining parental/guardian consent before we allow a young person to participate. Potential study participants will be made aware of the opportunity to participate in a project conducted by researchers at the University of New Mexico who visit the Bernalillo County Juvenile Detention Center. Adolescents (and later their parents) will be told that researchers at the University of New Mexico are developing programs meant to encourage healthy behavior among adolescents, and that there are two different programs being tested. They will also be informed that the researchers are interested in understanding who responds best to these interventions, and thus a number of individual difference measures, including genetic information and STI test outcome, will be collected. These procedures will be fully explained to both participants and their parents. Participants will be told that they will be involved in programs that discuss sensitive topics such as sexual behavior and alcohol and marijuana use. The researcher describing the study will be very explicit that participation is completely voluntary, and participation (or not) will in no way affect the young person's status in or treatment by the juvenile justice system. Once a young person expresses interest and signs the informed consent, University of New Mexico research staff will contact the parent or guardian by phone, explain all aspects of the study, read the consent form verbatim, obtain verbal consent over the phone, and answer

any questions the parent or guardian may have. These conversations will be tape-recorded, logged, and kept for proof of consent. A copy of the consent form will then be mailed to the parent or guardian. We place the highest priority on parents or guardians being completely informed about what their child is being asked to do, and on making sure that we are indeed getting consent from a parent or guardian. We have tried other methods of obtaining consent (e.g., mailing consent forms home) and have either not received any response or, importantly, have received consent of questionable validity. Further, this method does not allow parents/guardians to ask detailed questions they may have about the research prior to consenting. In almost 10 years of conducting research with vulnerable adolescents, we have found phone consent to be the most reliable way to assure that we obtain fully informed consent from parents/guardians. We have had no adverse events related to this method of obtaining consent.

vi) Potential risks

Adolescent participants are considered to be at minimal risk. There are a few potential risks associated with participation: potential discomfort involved in answering questions about sensitive sexual topics or in participating in discussions of sexual issues in the intervention or focus group activities, risk of collecting genetic material, breach of confidentiality, risk pertaining to prisoner status participants, and unanticipated risk.

(1) Risk seriousness and likelihood

Risks Pertaining to the Collection of Genetic Material: The collection of genetic material has become common-place within several research disciplines, and entails only minimal risk to study participants. Although research with genetic material is becoming more commonplace, official guidelines for the use of genetic material in research do not yet exist. Prior to initial consent, participants will be informed verbally and in writing, of the risks of genetic materials and the steps we will take to ensure confidentiality. All genetic material will be stored in Co-I Kent Hutchison's laboratory at the MRN. It is here that extraction of genetic material will occur. To ensure confidentiality, information regarding genetic composition will not be reported to corrections staff or any other individual outside of the direct collaborators on the project. This information will also have no bearing on the prisoner's status within the correctional system.

Risks Pertaining to the Collection of Urine: In the BCJDC, urine is already collected for STI testing from all female residents and from male residents who report symptoms consistent with STI infection. Facility staff informs us that they would ideally test all residents, but budgetary and labor constraints are prohibitive. Thus, urine collection and testing already occurs for a portion of facility residents, and it would ideally occur for all residents. We will ask participants who have been tested at the facility for permission to access their BCJDC records. Those who decline to share their records or have not already undergone a test will provide urine, which will be assayed for *Chlamydia Trachomatis* or *Neisseria Gonorrhoeae* at TriCore Reference Laboratories. At the 12-month follow-up session, all participants will provide urine, which will be assayed at TriCore. The only risk added by testing urine for STIs involves loss of privacy and confidentiality. However, we will use the same safeguards we use for other sensitive information gathered during the study (e.g., genetics results, self reports of drug use and sexual activity). TriCore staff, who perform the assays for *Chlamydia Trachomatis* or *Neisseria Gonorrhoeae*, will only be provided with a subject ID number; they will not have access to any personally identifying information, or any of the other data collected in the study. TriCore staff will inform us of the test results, and we will immediately contact participants who have tested positive. We will also complete

and submit a mandatory state reporting form required in the event of a positive test for Chlamydia and/or Gonorrhea.

Risks Pertaining to STI Treatment: In the event of a positive test for *Chlamydia Trachomatis* or *Neisseria Gonorrhoeae*, BCJDC staff (at baseline, if the participant is still in the BCJDC) or our research staff (at the 12 month follow-up, or at baseline if the participant has been released from the BCJDC between the time of urine collection and test results) will administer one gram Azithromycin or 400mg Cefixime, respectively. Meta-analyses indicate that these single dose treatments are approximately 97% effective at clearing microbial infection (Lau, Qureshi, & Azhar, 2002; Moran & Levine, 1995). This clearance rate is equivalent to alternative treatments that require repeat dosage over several days, and it maximizes the probability that the participant will clear the infection. Although other antibiotics (e.g., doxycycline) are cheaper and equally effective if taken correctly, they require the participant to comply with taking the medication over a lengthier treatment regimen. Given our population is composed of adolescents who frequently encounter difficult life events, in combination with well-established nonadherence to medical regimen in the broader treatment literature (e.g., DiMatteo, 2004; DiMatteo et al., 2007), we believe the more expensive, single-dose treatment will reduce the risk of the infection not being cleared.

Both of these antibiotics have very low risk of harmful pharmacological side effects. In fact, several states (including New Mexico) have standard expedited partner therapy (EPT) in the event of a positive test for Chlamydia or Gonorrhea. Under EPT, a health care provider can provide medication to a patient's partner without ever examining the partner and without any medical supervision over the partner's use of the medication. Hence, it is currently standard practice in New Mexico to provide these medications with no direct clinical supervision before, during, or after treatment.

Nevertheless, there can be relatively minor side effects of taking Azithromycin and Cefixime, include gastrointestinal distress and headaches. In extremely rare cases, individuals may experience chest pains, irregular heartbeat, muscle weakness, and seizure. Again, these types of reactions are very rare. EPT treatment policies (i.e., physicians providing medication to individuals whom they never see or monitor) underscore the safety of these medications. We will also mitigate risks by asking all participants and their parents if they are allergic to any medications and any antibiotics, and by asking if they are allergic to the specific antibiotics we will use and to possible alternative antibiotics. Please refer to the attached allergy checklist sheet we will use during the consent process.

However small, there are still risks associated with taking these medications. Extremely rare side effects (e.g., anaphylactic shock) can require emergency medical assistance. We have thus considered two procedures to minimize this risk: 1) having our staff treat participants in the field after being trained by Dr. Alberta Kong, a pediatrician who is advising the STI treatment phase of the study, and CTSC staff on recognizing severe side effects and contacting emergency health workers at the first sign of trouble, or 2) requiring participants to come to UNM's CTSC for treatment under the clinical supervision of medical staff, who can treat severe symptoms on site.

After seriously considering the risks and benefits associated with both options and consulting Dr. Kong and Carol Hartenberger, a nurse at the CTSC, we have decided that treatment delivery in the field by our staff is in the best interests of research participants. Although the consequences of rare side effects to medication can be minimized if antibiotics are administered within a medical setting, the probability of

participants coming to the CTSC for treatment is extremely low, meaning that a substantial portion of participants with active infections that are harmful not only to themselves but to their sexual partners will not receive treatment. Research suggests that participants – especially adolescent participants – will have a low rate of compliance if asked to come to a clinic for treatment. One study of appointment compliance with adolescents who were HIV+ and thus in dire need of clinical care showed that 33% of scheduled appointments were missed over a 6 month period (Rotheram-Borus et al., 1997) Moreover, several of our participants live far from the University (e.g., Rio Rancho) and do not have private transportation. Although we can pay for participants' bus fare, many of these participants do not live close to simple bus routes to UNM. Additionally, some participants may require transportation from their parents to reach UNM. Forcing participants to ask their parents for transportation to a medical clinic may make participants choose between declining treatment and endangering the confidential results of the STI test. The association of difficulty in facilitating transport to a clinic with non-adherence to medical regimen has been demonstrated in the clinical literature (O'Boyle et al., 2002), and treatment success rates have been shown to be higher for community versus facility-based directly observed treatment (van den Boogaard et al., 2009). Indeed, in a study using a population similar to ours, Cotter et al. (2002) report that they would have lost approximately 25% of their sample had they required all participants to come to a central office location. In sum, we anticipate that many participants who need treatment will go untreated if they are required to go to a clinic. The risks associated with failing to treat participants expeditiously for *Chlamydia Trachomatis* or *Neisseria Gonorrhoeae* infection include damage to the testes, prostate, epididymis, uterus, ovaries, fallopian tubes, and even joints and heart valves. Moreover, the majority of this population is sexually active. Delays in treatment will increase the incidence of transmission to infected individuals' partners. Indeed, cost effectiveness studies consistently favor directly observed treatment (DOT), even when provided by lay workers, over traditional extended or clinic-based therapies. The major reason DOT is favored is the cost of untreated infections both to the patient and to those at risk of transmission from the patient (c.f., Wilton et al., 2001).

Whereas requiring participants to come to a clinic for treatment will lead to delays in treatment and potentially a low rate of compliance, we have tremendous success (~90% compliance) when meeting the participant at a location near a their home (e.g., a fast food restaurant) and at a time convenient for them. This type of treatment delivery is ideal, since our staff can meet the participant at their earliest convenience, and the infection can be treated as quickly as possible. Moreover, our staff can follow the same procedures used in our existing post-intervention follow-up assessments. We will continue contacting the participant until a meeting time and location can be arranged. If the participant does not arrive at the meeting time and location, we will reschedule until our staff meets the participant and delivers treatment. At the time of treatment, our staff will watch the participant take the medication orally and confirm that it has been consumed. Our staff will remain with the participant for 30 minutes to monitor for any adverse effects. Our staff will be trained by Dr. Kong to recognize signs of severe adverse effects to the medication. In the event of a severe adverse effect (e.g., seizure, shock, fainting), our staff will immediately dial 911 and inform emergency medical operators of the medication and dosage delivered. During the 30 minutes of monitoring, our research staff will give the participant descriptions and contact information of clinics that can treat STIs in the event of future infections or further treatment requirements. Please refer to the attached sheet of resources we will provide participants.

In weighing the risks of treating participants in the field versus delayed or perhaps undelivered treatment, we contend that treating in the field presents the lowest risk. Treatment will be delivered more quickly, a higher rate of participants will receive treatment, and confidentiality will be better protected. Moreover, there is precedence for treating in the field. Using non-medically trained research staff similar to our staff, Auerswald et al. (2006) tested and treated homeless individuals in the San Francisco area for *Chlamydia Trachomatis* and *Neisseria Gonorrhoeae*. In the event of a positive test, they delivered the same treatment we are proposing with no reported adverse incidents. They concluded that field treatment of hard to reach populations such as that involved in this project is a feasible alternative to clinical treatment.

Risks Pertaining to Sensitive Topics: Participants may experience some discomfort when answering questions about sexual topics or while participating in discussions about sexual issues in the intervention. This concern is addressed by using trained intervention leaders with experience discussing sexual material. Additionally, prior to the intervention, all participants will be informed that participation is completely voluntary, they have the right to withdrawal their participation at any time, the have the right to refuse answering any questions for any reason, and they can choose to disclose personal information during the intervention.

Risks Pertaining to Loss of Confidentiality and Privacy: Participants will be informed that their privacy will be maintained in all published and written data resulting from the study, that their data will be identified with only a numerical ID code, and that all identifying information (e.g., name, phone number) will be kept in a locked location completely separate from the data files themselves. No information obtained in this study will be shared with prison officials, nor will any information in this study be shared with parents or guardians of the participants. The practices and procedures utilized in this study follow successful procedures utilized in our prior work.

Risks Pertaining to Prisoner Status: The Department of Health and Human Service's definition of "Minimal Risk" differs somewhat for prisoner populations. According to section 45 CFR 46.303(d) of the Department of Health and Human Safety, minimal risk for prisoners is defined as "the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of health persons." The procedures that we have proposed to undertake fall under the purview of this definition. We do not anticipate that anything encountered by our participants would create anymore risk than a non-prisoner population. However, because the use of prisoner populations adds additional risks, additional safety measures will be undertaken to ensure confidentiality and the voluntary nature of the participation.

A further issue with regard to the treatment of prisoners in research is that prisoners may only be involved in randomized studies when all versions of the treatment "have the intent and reasonable probability of improving the health or well-being of the subject" [see OHRP 46.306(a)(1)(iv)]. In the current study, participants in all 3 intervention conditions will focus on HIV/STD reduction, programming that is not currently offered at the detention facility. Adolescents involved in this study will continue their usual detention center programming and will receive the same information that those not participating in the study will receive. In addition to this "standard of care" offered by the facility, participants in the comparison condition will complete baseline pretest measures, review basic HIV/STD transmission facts, and receive a workbook reinforcing the information in the presentation. They will also view a film on sexually transmitted diseases, their symptoms, and their prevention, followed by

discussion and Q&A on how HIV/STDs can be prevented. Participants in the comparison condition will also be given the same Albuquerque-metro area sexual health resource list that is provided in the SRRI+ETOH+THC and SRR+ETOH conditions. The intervention leader will encourage the adolescents to ask any questions they have about HIV or STDs and then participants will complete a posttest assessment.

The comparison condition in the current study will be neither a 'no-treatment' nor a 'treatment as usual' condition. We will provide considerably more HIV/STD programming over what adolescents would usually receive at the detention center. This research should be permissible under OHRP 46.306 (a)(1)(iv) – all three conditions have a reasonable probability of improving the health and well-being of participants. Participants in the information-only condition will receive treatment that exceeds "standard of care" and as a result, these participants stand to gain from participating in the study.

Unanticipated risks: Any experiment may involve anticipated risks. Any identified risks will be reported immediately to UNMHSC HHRC for consideration.

(2) Alternative treatments

As this is strictly a research project, the only alternative is to not participate.

(3) Circumstances for terminating the protocol

If a participant is disruptive, uncooperative, threatening, or physically violent towards other participants or the intervention leader during an intervention session, his or her participation will be terminated. Also, if a participant chooses to stop participating for any reason, participation will be terminated. The entire study may be terminated if the PI or other governing official discovers serious concerns about participants' safety or inadequate performance or rate of enrollment; the study objectives have been obtained according to the pre-established statistical guidelines; or in the unlikely event that the PI should retire or be phased out and no other additional investigators are able to succeed her role.

vii) Procedures for minimizing risk

If at any time, a research staff member suspects a participant suffers from an unidentified psychological disorder (i.e., depression, anxiety, schizophrenia), or if a participant appears to have significantly increased his or her alcohol or drug consumption, the research scientist will provide the participant with information about clinical services. Our trained research scientists are not licensed clinical psychologists, and therefore are unable to give clinical advice. However, they will provide appropriate referrals if necessary and will assist participants with contacting referral sources if assistance is requested. The Department of Psychology, CASAA, and MRN maintain an updated list of CYFD clinical services and local community practitioners for most psychiatric and substance disorder treatment services for noninstitutionalized participants. Researchers may also suggest opportunities for treatment within the detention facility if necessary. Importantly, researchers will not break confidentiality unless the participant presents a clear danger to him/herself or others.

Additional Protections for Incarcerated Populations: In addition to requirements under 45 CFR 46(a), the Department of Health and Human Services has as set of additional requirements for investigators and IRBs when prisoners are involved.

viii) Expected benefits

All participants will have the opportunity to examine their own sexual risk behavior in the context of completing measurement instruments, and will have the opportunity to ask a research staff member knowledgeable about STD/HIV and substance use issues any questions they may have. Participants in all three intervention conditions will receive the added benefit of an intensive health behavior change intervention that may successfully reduce their risk for contracting sexually transmitted diseases including HIV and for being involved in an unplanned pregnancy. The costs associated with participating have been minimized via the consent procedures and procedures for maintaining confidentiality described above. The minimal costs associated with participation in this research are reasonable in relation to the anticipated benefits to the participants themselves. In terms of benefits to others, a demonstration that one or more of the sexual risk reduction interventions is successful has great potential to benefit all young people in New Mexico detention centers and beyond. Should the interventions be successful, all materials and training necessary to conduct the intervention will be given to the detention facility, we will train them in their use, and they can immediately begin implementing the intervention with their detainees. Given the lack of such programming in such facilities currently, a low-cost, easily implemented, one-time intervention with documented efficacy at reducing sexual risk behavior would be a vast improvement over the current situation.

Tests and treatment for *Chlamydia Trachomatis* and *Neisseria Gonorrhoeae* perhaps benefit participants most directly. Left untreated, these bacteria can cause epididymitis, sterility, and pelvic inflammatory disease, as well as prolonged painful symptoms (e.g., pain during urination). Infections are often asymptomatic, and asymptomatic individuals may unwittingly experience serious personal consequences of infection, and they may spread infection to others. The free test and treatment provided in this study has the potential to mitigate devastating personal consequences of these STIs.

From a larger perspective, the findings of this investigation will increase the body of knowledge about the influence of alcohol and marijuana use on risky sexual behavior, and will demonstrate whether an HIV risk reduction intervention that incorporates an alcohol and marijuana risk reduction component or an alcohol risk reduction component has greater potential for sexual risk reduction than a sexual risk reduction intervention alone. From a theoretical perspective, a demonstration that an intervention based on a theoretical model of condom use intentions and behavior articulated to high-risk criminally-involved adolescents would be important evidence for the utility of the strategy of developing tailored models of health behavior. In addition, a demonstration that it is the substance use content, rather than the intervention delivery modality of a group motivational enhancement therapy approach, has great potential for the development of comprehensive risk reduction intervention technology for young people at risk for both substance use and high risk sexual behavior. Finally, the information on genetic moderators of program effectiveness will be highly useful for the development of future programs.