

# Attachments A & C

## Attachment A

HPTN Ancillary Application: Description of proposed study

- Alcohol Use in the Context of HIV Sexual Risk Behavior among Black MSMW

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### **Ancillary study justification:**

This proposed study is defined as an ancillary study to the HIV Prevention Trials Network Study 061 as it will only consist of retrospective data analysis not involving study endpoints.

### **Study purpose/design:**

Data indicates high HIV and STI prevalence rates among Black men who have sex with men (MSM) in the United States (1, 2). Unprotected intercourse has been identified as a risky sexual behavior associated with HIV/STI transmission, and research has found that alcohol use in the context of sexual behavior increases the likelihood of individuals engaging in risky (i.e., unprotected) behaviors (3). While this association has been demonstrated among MSM broadly, the effects of alcohol on sexual risk taking and its underlying mechanisms are not fully understood among Black men who have sex with men and women (MSMW) specifically (4). MSMW may confer a unique risk for HIV/STI infection as well as transmission among both men and women partners (4). Furthermore, the ability for condom negotiation, sexual positioning, and overall risk among such men may be associated with the gender of their sexual partner(s), and may be further complicated by alcohol use (4).

### **Rationale**

The goal of the proposed project is to advance our understanding of the relationship between alcohol use and sexual risk behaviors among Black MSMW by conducting a multilevel examination of main effects and moderating variables. These results will inform the risk-reduction content of HIV/STI prevention efforts by identifying individuals who are most vulnerable to sexual risk-taking in the context of alcohol use.

The proposed project will focus on three specific aims:

- 1) The primary objective is to examine the association between alcohol use within the context of sexual activities and the use of protected sexual behaviors (i.e. condom use) among Black MSMW in 6 U.S. cities. An additional objective is to examine the role of several moderators: age, partner gender, partner type (i.e. casual, primary, or trade/exchange partners), level of alcohol use problems, sexual identity, depressive symptoms, and HIV status at enrollment.
- 2) The secondary objective of the proposed project is to model the relationship between alcohol use and condom use at both the distal (past 6 months) and proximal (most recent episode) levels of analysis.
- 3) The third objective is to understand the stability of these behaviors through time (i.e.

baseline, six, and twelve month time points).

It is hypothesized that alcohol use in the context of sex will decrease men's ability to engage in protected sexual behaviors (i.e. condom use). This relationship is expected to be particularly strong among: 1) younger men, 2) sex with primary partners, 3) men with high levels of alcohol use problems, 4) men failing to have a behavior-congruent sexual identification, 5) men exhibiting depressive symptoms, and 6) sero-concordant sexual encounters.

**Methods:**

Data analyses will consist of logistic regression to analyze condom use as an outcome, which is in turn predicted by alcohol use and the moderator, each tested separately, (e.g.  $\text{condomuse} = \text{ALC} + \text{HIVstatus} + \text{ALC} * \text{HIVstatus}$ ). This will be done for both the proximal and distal levels of analysis. For the purposes of the analyses, only men reporting sexual activity with both a man and a woman in the past 6 months will be included in analyses. At the proximal level we will control for other substance use two hours prior to, or during, sex. This will allow for examination of the unique contribution of alcohol to risk behaviors.

Demographic Factors: Age, city/HPTN site, sexual identity, education, income, employment status, HIV status at enrollment.

Psychosocial Factors: Depressive symptoms, alcohol use problems, partner gender, partner characteristics (i.e. casual, primary, or trade/exchange partners).

Sexual Risk Behaviors: Sexual risk behaviors are defined as unprotected receptive or insertive anal or vaginal sex.

**Assessments to be performed:**

No additional assessments will be performed.

**Necessary staff:**

This ancillary study will not require any additional staff.

**Where activities carried out:**

Vincent is a graduate student at University of California, Los Angeles and will receive primary mentorship from Lara Ray, Ph.D. in the clinical psychology department. They have a weekly meeting schedule. The analyses from this project will be used as part of Vincent's dissertation project.

**Primary study:**

This ancillary study will not have any impact on the primary study as it is completed during the time of data analysis.

## References

1. Centers for Disease Control and Prevention. HIV among gay and bisexual men. In; 2012.
2. Centers for Disease Control and Prevention. HIV among African Americans. In; 2012.
3. Mustanski BS, Newcomb ME, Du Bois SN, Garcia SC, Grov C. HIV in young men who have sex with men: A review of epidemiology, risk and protective factors, and interventions. *Journal of Sex Research* 2011;48(2 - 3):218 - 253.
4. Spikes PS, Purcell D, Williams KM, Chen Y, Ding H, Sullivan P. Sexual risk behaviors among HIV-positive Black men who have sex with women, with men, or with men and women: implications for intervention development. *American Journal of Public Health* 2009;99(6):1072-1078.

## **Attachment C**

### **Description of data management/statistical assistance**

Vincent will arrange data management with SCHARP via scheduled phone meetings and consultation on data sets. Vincent will require SCHARP assistance for assessing data sets but not for data analysis.