



Uganda Russia Boston Alcohol Network for  
Alcohol Research Collaboration on HIV/AIDS

## **Impact of Heavy Alcohol Use on Pre-ART HIV Disease - Uganda ARCH Cohort Funded by the National Institute on Alcohol Abuse and Alcoholism (grant no. U01 AA20776)**

The Alcohol Drinking Effects on Progression prior to Treatment (ADEPT) Study is the Uganda cohort of the Uganda Russia Boston Alcohol Network for Alcohol Research Collaboration on HIV/AIDS (URBAN ARCH) Consortium, which is a member of the National Institute on Alcohol Abuse and Alcoholism's Consortiums for HIV/AIDS and Alcohol Research Translation (CHAART) Initiative. The CHAART Initiative aims to build upon pre-existing cohorts to create a group of research cohort studies to accurately characterize alcohol use and its consequences among HIV-infected adults, and to test alcohol interventions. The main objective of the URBAN ARCH Consortium is to examine the effects of alcohol use on HIV disease and to mitigate its harmful effects. More information on the URBAN ARCH Consortium can be accessed here: <http://www.urbanarch.org/>.

The URBAN ARCH Consortium consists of three cohorts, as well as Administrative and Biostatistics and Data Management Cores. The Uganda ARCH Cohort is one of the three cohorts and has the following specific aims:

1. To determine the effect of heavy alcohol consumption on HIV disease progression prior to the start of ART.
2. To explore the possible biological and behavioral pathways by which heavy alcohol consumption may accelerate HIV disease progression prior to ART initiation.

### **Study Design**

- The Uganda ARCH Cohort study is observational and seeks to determine the effect of alcohol consumption on HIV disease progression prior to ART.
- The Uganda ARCH Cohort will include approximately 210 self-reported past year abstainers from alcohol and 440 self-reported past year drinkers.
- Baseline and follow-up study visits occur every 6 months, with an interim study check-in 3 months after each visit to minimize loss to follow-up.
- Study participants are followed until one of the following occurs: the patient initiates ART, the data collection period ends, the participant moves out of the area, or the participant dies. The maximum length of follow-up will be 3 years.
- Data collected at each study visit include: a research assistant administered questionnaire, blood specimens, alcohol breath testing, and medical record review. At each visit, blood specimens are tested for CD4 cell count and phosphatidylethanol (PEth, a biomarker of recent alcohol use); viral load is tested at baseline only. Additionally, a sub-sample of baseline samples (n = 250) will be tested for microbial translocation (sCD14), immune activation (IL-6), Hepatitis B virus (HBsAg), and liver fibrosis (FIB-4).

- *Primary outcome:* CD4 cell count (cells/mm<sup>3</sup>) at each study visit.
- *Main independent variable:* Recent heavy alcohol consumption, defined as a positive Alcohol Use Disorders Identification Test – Consumption (AUDIT-C) score ( $\geq 3$  for women, and  $\geq 4$  for men), or a positive ( $\geq 50$ ) PEth result.

## **Eligibility for Uganda ARCH Cohort**

### *Inclusion Criteria:*

- Not currently or previously on ART, and not booked to start ART within 3 months
- Diagnosed with WHO Stage I or II (asymptomatic or mild disease), and CD4 cell count  $>350$  cells/mm<sup>3</sup>
- Fluency in Runyakole (the local language) or English
- Residence within 60km or 2 hours of the ISS Clinic
- Age 18 or older
- Ability to give informed consent

**Primary Recruitment Site:** Uganda ARCH Cohort participants are recruited from the Immune Suppression Syndrome (ISS) Clinic of the Mbarara Regional Referral Hospital in Mbarara, Uganda. The ISS Clinic is the primary municipal clinic for HIV-infected adults in southwestern Uganda, and is the second largest HIV clinic in Uganda.

### Assessment Summary – Uganda ARCH Cohort Study Time Points

Information Collected	Study Time Point						
	Baseline	6- mos	12- mos	18- mos	24- mos	30- mos	36- mos
<b>Study Interview – administered by research assistant</b>							
Demographics	X						
Alcohol							
Lifetime alcohol use	X						
Alcohol Use Disorders Identification Test (AUDIT, 1 year)	X		X		X		X
Alcohol Use Disorders Identification Test-Consumption (AUDIT-C, 3 months)	X	X	X	X	X	X	X
Current alcohol consumption	X	X	X	X	X	X	X
Cost of alcohol	X	X	X	X	X	X	X
30-day timeline follow-back (TLFB) alcohol	X	X	X	X	X	X	X
Influence of HIV clinic counselors	X	X	X	X	X	X	X
Adherence to multivitamins, OI prophylaxis	X	X	X	X	X	X	X
HIV Symptom Index	X	X	X	X	X	X	X
Physical Functioning Scale (MOS-HIV)	X	X	X	X	X	X	X
Household Food Insecurity Access Scale (HFIAS)	X		X		X		X
Lifetime tobacco/ substance use	X						
Current tobacco/substance use	X	X	X	X	X	X	X
Alcohol expectancies	X		X		X		X
Most recent sexual experiences	X	X	X	X	X	X	X
Social Support Scale	X						
Social Desirability Scale	X						
Center for Epidemiologic Studies Depression Scale (CES-D)	X	X	X	X	X	X	X
Ironson-Woods Spirituality/Religiosity Index	X						
Interviewer Confidence	X	X	X	X	X	X	X

MINI Alcohol	X		X		X		X
<b>Biological tests and specimens</b>							
Breathalyzer	X	X	X	X	X	X	X
Dried Blood Spot (DBS): PEth	X	X	X	X	X	X	X
Whole blood (4ml): CD4	X	X	X	X	X	X	X
Plasma: viral load	X						
Plasma: Fib-4 score*	X						
Plasma: sCD14, IL-6, D-dimer*	X						
Plasma: HBsAg*	X						
Plasma: stored for future research	X		X		X		X
*sub-sample only							

## Uganda ARCH Study Team – Contact Information

### Investigators

**Judy Hahn, PhD, MA**

Principal Investigator, Uganda ARCH

[Judy.hahn@ucsf.edu](mailto:Judy.hahn@ucsf.edu)

Phone: 415-597-4961

**Peter Hunt, MD**

Co-Investigator, Uganda ARCH

[phunt@php.ucsf.edu](mailto:phunt@php.ucsf.edu)

Phone: 415-476-4082 x345

**Winnie Muyindike, MBChB, MMED**

Co-Investigator, Uganda ARCH

[wmuyindike@gmail.com](mailto:wmuyindike@gmail.com)

Phone: 256 – 772-52-1619

**Jeffrey Samet, MD, MPH, MA**

Co-Investigator, Uganda ARCH

Principal Investigator, URBAN ARCH

Administrative Core

[jsamet@bu.edu](mailto:jsamet@bu.edu)

Phone: 617-414-7288

**Starley Shade, PhD**

Co-Investigator, Uganda ARCH

[starley.shade@ucsf.edu](mailto:starley.shade@ucsf.edu)

Phone: 415-597-9254

### Project Management

**Nneka Emenyonu, DrPH, MPH**

Project Director, Uganda ARCH

[emenyonun@ucsf.edu](mailto:emenyonun@ucsf.edu)

Phone: 415-597-9346