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Project ACCEPT: Engaging Newly Diagnosed HIV+ Youth in Care

A Multi-Center Study of the Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN)

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REQUIREMENTS FOR SITE PARTICIPATION

Each enrolling Adolescent Medicine Trials Unit (AMTU) should have the following capabilities:

- A pool of potential participants i.e., newly diagnosed youth as Human Immunodeficiency Virus (HIV)-positive within the past 12 months (+3 months), between the ages of 16-24 inclusive at the time of consent;

- Ability to recruit approximately 16 participants (12 males and 4 females) in up to three waves (for an approximate total of 48 participants);

- Ability to hire and supervise two interventionists (one of each gender to match participants) who are Master's-level (preferred) mental health providers with training in counseling and previous clinical experience in facilitating individual and group sessions with adolescents as determined by staff members at the respective AMTU. Protocol co-chairs are available for consultation if needed.

- Ability to hire and supervise two peer facilitators (one of each gender to match participants) who are HIV-positive, have previous experience as a peer facilitator or possess the skills necessary for co-facilitation of the sessions, demonstrate maturity, and are of an age similar to that of the participants (although age will not be a limiting factor) as determined by staff members at the respective AMTU and in consultation with either of the protocol co-chairs;

- Ability to designate Study Coordinator (SC) (or other clinical research staff) time for recruitment and retention of participants and administration of Audio Computer-Assisted Self-Interview (ACASI) assessments; and

- Adequate space to accommodate individual assessments and intervention sessions, including a separate room for group sessions, as needed.

STUDY MANAGEMENT

Before the recruitment and enrollment of participants, the participating ATN study sites must have the protocol and consent form(s) approved by their local Institutional Review Boards (IRBs). In addition, ATN study sites must receive protocol registration approval from the ATN Data and Operations Center (DOC). All original, approved documents must be maintained at the ATN study site. A detailed description of site and protocol registration procedures is included in Chapter 6 of the ATN Manual of General Operations (MOGO).

All queries for this protocol should be sent to the ATN 108 protocol team using the ATN Protocol Query and Notification System (QNS) accessible via the ATN website (https://www.atnonline.org). The appropriate team member will respond to queries generally within 48 business hours via the ATN QNS and copy the other team members. The Protocol Specialist, with the help of other ATN DOC personnel and/or NICHD, if necessary, will answer general protocol implementation, eligibility and Case Report Form (CRF) completion queries. The Protocol Chair or his/her designee will respond to study and participant management, exemptions and/or adverse event queries. This study follows the ATN Policy for Guidance for Safety and Impact Reporting located in Appendix I-B of the ATN MOGO. Queries and replies will automatically be archived at the ATN DOC. The Protocol Specialist will post those queries deemed relevant to all sites on the ATN website, where they will be available for future reference.

This study will use the ACASI to collect study data. All questions related to the ACASI should be directed to the ATN Help Desk at the ATN DOC. The ATN Help Desk can be contacted either by calling the toll-free ATN ACASI helpline at (888) 222-6358 or by e-mailing ATNHelp@westat.com. The ACASI Help Desk at the ATN DOC will be available to provide technical assistance to sites.

For protocol registration issues, contact the ATN Regulatory Affairs Office at Regulatory@westat.com.

For Remote Data Capture (RDC) issues, contact Sarah Howell at SarahHowell@westat.com, the ATN 108 Data Research Associate.

For Web Randomization issues, contact the ATN Webmaster at ATNwebmaster@westat.com.

LIST OF ABBREVIATIONS

ACCEPT	Adolescents Coping, Connecting, Empowering and Protecting Together
ACASI	Audio Computer-Assisted Self-Interview
AIDS	Acquired Immunodeficiency Syndrome
AMTU	Adolescent Medicine Trials Unit
ARTAS	Antiretroviral Treatment and Access Study
ASSIST	Alcohol, Smoking and Substance Involvement Screening Test
ATN	Adolescent Medicine Trials Network for HIV/AIDS Interventions
BLG	Behavioral Leadership Group
BSI-18	Brief Symptom Inventory – 18
CDC	Centers for Disease Control and Prevention
CES-D	Center for Epidemiologic Studies Depression Scale
CFR	Code of Federal Regulations
CLEAR	Choosing Life: Empowerment, Actions, Results
CRF	Case Report Form
CUSES	Condom Use Self-Efficacy Scale
DAIDS	Division of AIDS
DHHS	U.S. Department of Health and Human Services
DOC	Data and Operations Center
DOT	Directly Observed Therapy
EC	Ethics Committee
FIPS	Federal Information Processing Standards Publication
GCP	Good Clinical Practices
HAART	Highly Active Antiretroviral Therapy
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Virus
HIV-HRQOL	HIV Health Related Quality of Life Scale
HRSA	Health Resources and Services Administration
ICH	International Conference on Harmonization
IGES	Intervention Group Environment Scale
IMB	Information-Motivation-Behavioral
IMPAACT	International Maternal-Pediatric-Adolescent AIDS Clinical Trials Group
IRB	Institutional Review Board
ITT	Intent-To-Treat
LGBTQ	Lesbian, Gay, Bisexual, Transgender and Questioning
MAHIVS	Mental Adjustment to HIV Scale
MI	Motivational Interviewing
MOGO	Manual of General Operations
MSM	Men who have Sex with Men
MTC	Mother To Child
NICHD	National Institute of Child Health and Human Development
NIDA	National Institute on Drug Abuse
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NIST	National Institute of Standards and Technology
OAR	Office on AIDS Research
OC-RDC	Oracle Clinic Remote Data Capture
OHRP	Office of Human Research Protection
OIs	Opportunistic Infections

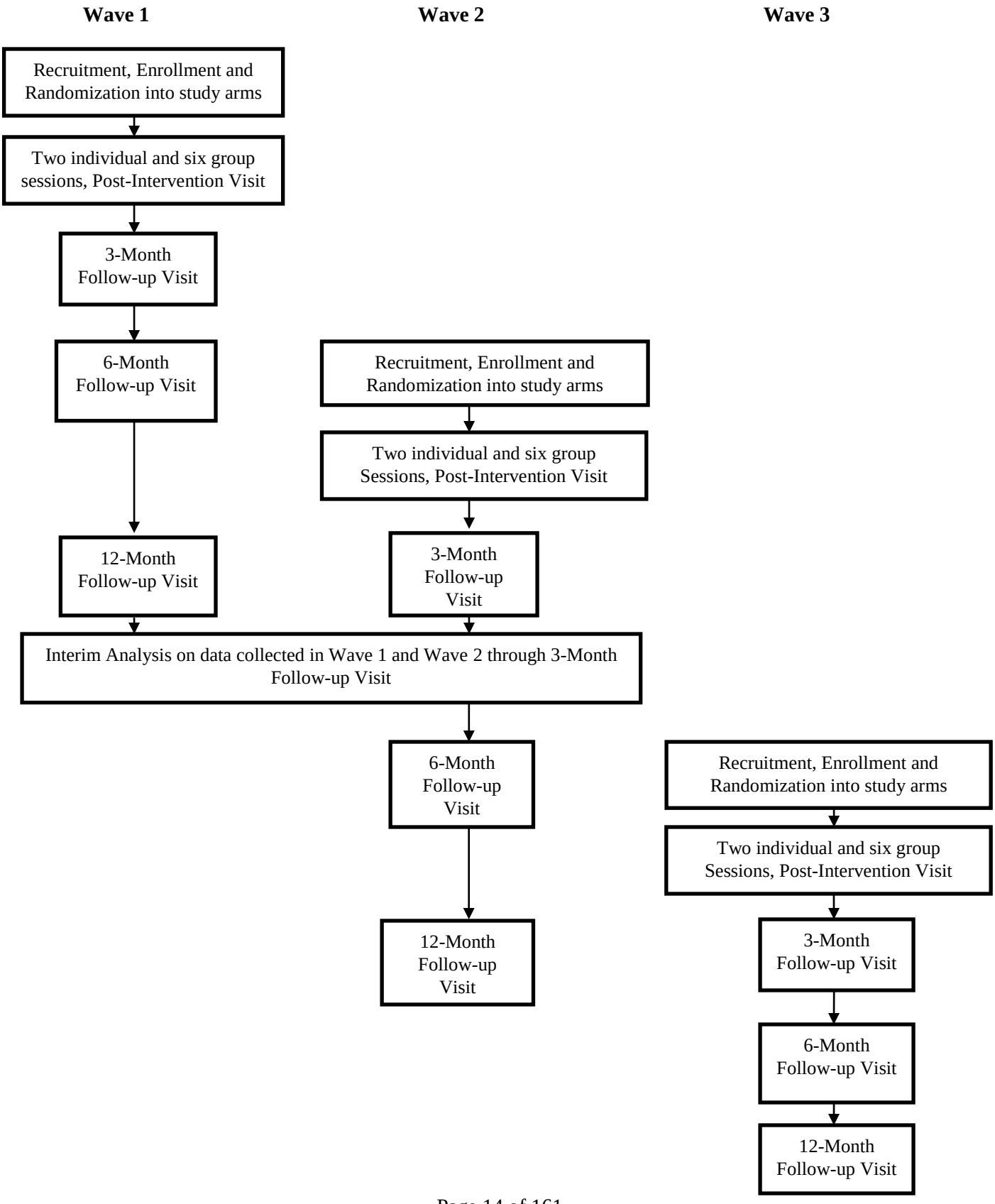
PACTG	Pediatric AIDS Clinical Trials Group
PI	Principal Investigator
PID	Patient Identification Number
PLWH	People Living with HIV/AIDS
QA	Quality Assurance
QNS	Query and Notification System
RCT	Randomized Controlled Trial
RDC	Remote Data Capture
RRM	Random Regression Modeling
SC	Study Coordinator
SEF	Session Evaluation Form
SID	Study Identification Number
SSAS	Social Support for Adolescents Scale
STD	Sexually Transmitted Diesease
TREAT	Therapeutic Regimens Enhancing Adherence in Teens
TLC	Together Learning Choices
VAS	Visual Analogue Scale
WHO	World Health Organization
YMSM	Young Men who have Sex with Men

STUDY ABSTRACT

DESIGN:	The proposed study is a two-group randomized repeated measures design that will examine the efficacy of Project ACCEPT (Adolescents Coping, Connecting, Empowering and Protecting Together) to improve engagement in care among youth newly diagnosed with HIV at five AMTU sites across the United States. Youth will be randomized into one of two study arms; Project ACCEPT, the intervention, or HEALTH, the health education attention-controlled comparison condition. Both arms consist of two individual sessions followed by six group sessions and a final individual session which is expected to take approximately nine weeks after which youth will have four follow-up visits at the following time points: • post intervention (immediately after the last session); • 3 months post the last session; • 6 months post the last session; and • 12 months post the last session. The trial will be repeated in up to three waves.
SAMPLE SIZE:	Approximately 240 youth (180 males and 60 females) are expected to be enrolled over three waves. Each site will enroll approximately 48 youth (16 per wave (12 males and 4 females)) over three waves.
POPULATION:	HIV-positive youth who are newly diagnosed within the last 12 (+ 3 months) and are between the ages of 16 and 24 years old.
INTERVENTION:	The intervention, Project ACCEPT, combines weekly individual and group sessions that address a range of issues that impact engagement in care for youth living with HIV, including stigma, disclosure, health relationships, substance use, and future life plans. The comparison condition, HEALTH, matches Project ACCEPT in number of sessions and duration. The weekly sessions will cover information on alcohol, drugs, HIV and other sexually transmitted diseases (STDs) to meet the ethical responsibility to provide risk reduction information to youth assigned.
STRATIFICATION:	Male youth at each site will be randomized, to either Project ACCEPT or HEALTH, in a 1:1 ratio. Each participating site that has sufficient female youth for both study arms will be randomized in a 1:1 ratio. Sites without sufficient female youth for both study arms, but with at least two female youth will be randomized to one of the study arms. It is expected that not all sites will have female participants in each wave. Youth will be separated by gender to participate in group sessions.

DURATION:	The total duration for this study is approximately three years. Each participant regardless of group assignment will be on study for approximately one year.
PRIMARY AIM:	To conduct a randomized controlled trial to examine the efficacy of Project ACCEPT compared with an attention-controlled health education comparison intervention (HEALTH). The goals of the intervention are to improve engagement in care, decrease psychosocial barriers to care, and decrease sexual risk for youth newly diagnosed with HIV.
EXPLORATORY AIM:	To explore the relationship between HIV biomarkers (i.e., CD4 and viral load) and participant's level of engagement in care.
STUDY HYPOTHESES:	1. Participants in Project ACCEPT will demonstrate greater engagement in care, as measured by HIV medical appointments and engagement with medical providers, compared to HEALTH participants. 2. Participants in Project ACCEPT will show decreases in psychosocial barriers to engagement in care, including improved knowledge, decreased psychological distress, decreased stigma, and increased social support, compared to HEALTH participants. 3. Participants in Project ACCEPT will have fewer episodes of unprotected sex, and fewer new diagnoses of STDs compared to HEALTH participants.
DATA COLLECTION:	Data will be collected primarily though self-report questionnaires administered through ACASI and abstraction from the participant's medical record. Each session (individual and group) of both Project ACCEPT and HEALTH will be digitally recorded for review by the Project Director for consistency, accuracy and adherence to the condition manuals.
MONITORING:	Routine team monitoring of untoward events identified during the study will rely on site staff notification via the ATN QNS, a real-time, web-based interactive reporting system. Sites will also record and enter in the study database, untoward events occurring during study participation, which will be reviewed during the protocol team's implementation monitoring calls.

PROTOCOL SCHEMA



1.0 INTRODUCTION

1.1 Overview

In the United States (U.S.), it is estimated that over one-third of all new HIV diagnoses are among people under the age of 29 (Centers for Disease Control and Prevention [CDC], 2009). The vast majority of infections among youth occur through sexual activity (CDC, 2008) indicating that despite prevention efforts, youth are extremely vulnerable to HIV infection. Once these youth receive an HIV diagnosis, they must then contend with adjusting to the reality that they are living with a chronic, infectious health condition that will require continual medical management for the rest of their life.

Engagement in medical care is crucial for youth diagnosed with HIV in order to improve medical outcomes (i.e., access to antiretroviral (ARV) medication, viral suppression, survival), psychological outcomes (i.e., psychosocial functioning, quality of life), and public health outcomes (i.e., viral transmission to others via sexual contact and lowering community viral loads [Das et al., 2010]). Despite the critical need for those diagnosed with HIV to engage in care, it is estimated that 20%-40% of HIV-infected individuals fail to attend a clinic visit within 3–6 months after receiving their HIV diagnosis (Mugavaro et al., 2007). Furthermore, retention-in-care rates decrease with age, indicating that young adults are most at risk for being lost to follow-up (Ashman, Conviser & Pounds, 2002; Naar-King et al., 2007).

Adolescents and young adults who test positive for HIV are often confronted with a range of difficulties as they try to integrate traditional adolescent developmental issues with the burden of living with a highly stigmatized illness. These difficulties, in turn, create barriers for adequately engaging in care. One such barrier is psychological distress, which has been associated with increased participation in sexual and substance use risk behaviors (Murphy et al., 2001a) as well as decreased adherence to (ARV) therapies (Hosek, Harper, & Domanico, 2005; Murphy et al., 2001b). Other barriers include lack of knowledge, lack of social support, and internalized stigma. These challenges are heightened during the first year after receiving an HIV diagnosis as youth struggle with initial acceptance of their diagnosis, feelings of depression/isolation, fears of illness/physical symptoms, and anxiety regarding disclosure to others (Hosek, Harper, Lemos, & Martinez, 2008). Given the potential for negative medical, psychological, and public health outcomes among youth newly diagnosed with HIV, interventions are urgently needed. This project will address the current gap in scientific knowledge regarding how to best assist adolescents and young adults who are newly diagnosed with HIV engage in health care in order to improve medical, psychological, and public health outcomes.

Project ACCEPT (**A**dolescents **C**oping, **C**onnecting, **E**mpowering, and **P**rotecting **T**ogether) development activities, acceptability and feasibility studies have been completed by the investigative team through earlier work with the ATN – ATN 055 and ATN 068. ATN 055 was a qualitative investigation of the challenges, strengths, and needed areas of support associated with receiving an HIV diagnosis among youth living with HIV. ATN 055 was theoretically grounded in Wallander and Varni's (1995) Disability-Stress-Coping Model of adjustment, which is based in a risk and resistance theoretical framework and is one of the most researched models related to the health and functioning of adolescents living with chronic illness. Information was elicited from individual interviews with medical and mental health providers, as well as case managers, regarding the intervention needs of youth (ages 16-24) newly diagnosed with HIV. Focus groups and individual interviews were then conducted with HIV positive youth who had been diagnosed within the past two years to identify the challenges, strengths, and needed areas of support/assistance associated with receiving an HIV diagnosis in order to ultimately improve engagement in care. Qualitative data from these interviews and focus groups were analyzed and used to guide the development of an intervention outline for Project ACCEPT. Project ACCEPT combined three

individual and nine group sessions aimed at addressing a range of issues that impact engagement in care for youth living with HIV, including stigma, disclosure, healthy relationships, substance use, and future life planning.

In ATN 068 the development of the intervention manual, training of interventionists and peer facilitators, and implementation of a treatment only pilot trial of Project ACCEPT to examine the acceptability, feasibility, and initial effects of the intervention across four ATN sites (Chicago, New York, Memphis, and Miami) was completed. Analysis of process evaluation measures showed strong acceptability ratings, high overall satisfaction with the intervention, and low attrition (4%). Additionally, promising effect sizes in changes over time in multiple areas, including improved HIV knowledge (d=.52), decreased depressive symptoms (d=.33), decreased stigma (d=.36), increased peer support (d=.35), and increased formal support (d=.20) were found. Furthermore, the overall number of missed medical appointments decreased at both the immediate-post and three-month follow-up, with effect sizes of d=.30 and .15, respectively. Participants also demonstrated increases in their comfort level with asking their doctor questions (76%, 85%, and 87% at baseline, post-intervention, and three-month follow-up). In post-intervention focus groups, staff and participants reported sustained engagement in care. Clinic staff discussed marked improvements in youth's perceptions regarding the role of health care professionals' ability to influence positive health outcomes. Youth also expressed improvements in motivation to seek information and consult with their health care providers on health-related issues. Thus, there is sufficient promising evidence to move Project ACCEPT into a controlled trial design to test for preliminary efficacy.

For the current project, an adaptive trial design will be used (including interim data analyses between each wave with stopping rules for futility or promise) to conduct a randomized controlled trial (RCT) of Project ACCEPT compared to the health education attention-controlled comparison condition, HEALTH, by randomizing 240 youth (120 to ACCEPT, 120 to HEALTH; both conditions separated by gender) newly diagnosed with HIV within the past 12 months recruited from five ATN sites. All participants will complete a behavioral and psychosocial assessment at baseline, immediate post-intervention, 3, 6, and 12-months post-intervention. Medical record reviews for each participant in order to accurately document medical appointments, monitor HIV biomarkers (CD4, viral load) as well as new sexually transmitted infection (STD) diagnoses will be conducted.

1.1.1 Background and Significance

1.1.1.1 Epidemiology of HIV among Youth

In the U.S., it is estimated that at least 14% of all new HIV/ Acquired Immunodeficiency Syndrome (AIDS) diagnoses are among people under 25 years of age, and the vast majority of these infections occur through sexual activity (CDC, 2008). In 2006, a total of 5,396 young people received a diagnosis of HIV/AIDS, and a cumulative total of 21,890 young persons were living with HIV/AIDS in the 34 areas with name-based reporting (9,024 females and 12,866 males). Additionally, owing to the long delay in developing symptoms associated with HIV infection, many of the young adults diagnosed in the 25-29 age groups were probably infected during adolescence or young adulthood. The ratio of male to female adolescents/young adults with an HIV diagnosis increases with age. In 2007, females accounted for 31% of adolescents aged 13-19 who were diagnosed with HIV, compared with 23% of young adults aged 20-24 (CDC, 2009).

In 2006, African Americans had the highest rates of new HIV/AIDS diagnoses, as well as the highest rate for those living with HIV/AIDS, when compared to all other ethnic groups. Rates among African American youth were three to five times higher than those among Hispanics, the population that had the second highest rates (CDC, 2009). African Americans accounted for 72% of HIV/AIDS diagnoses among 13-19 year olds, and 61% of diagnoses among 20-24 year olds (CDC, 2009). From 2001-2006, male-to-male sex was the largest HIV transmission category in the U.S. and the only one associated with an

increasing number of HIV/AIDS diagnoses (CDC, 2008). Of all age groups of men who have sex with men (MSM), HIV/AIDS increased most among young MSM (YMSM) ages 13-24. Among YMSM aged 13-24, young African American MSM had the most dramatic increase in diagnoses – from 938 cases in 2001 to 1811 cases in 2006 – an increase of 93% (CDC, 2009). HIV/AIDS also disproportionately affects Latino adults and adolescents, who account for 20% of new HIV infections while representing 16% of the total U.S.US population (2009). The incidence of AIDS for adult and adolescent Latinos in 2009 was nearly three times higher than that among their non-Hispanic white counterparts (2009). Latino men account for the majority of all new infections (79%), with Latino MSM accounting for 81% of all new infections among Latino men and 20% of all MSM. Nearly half of new HIV infections among Latino MSM occurred in those under 30 years of age. These epidemiological data demonstrate that despite multiple prevention efforts aimed at thwarting the spread of HIV, significant numbers of adolescents and young adults are still becoming infected with HIV on a consistent basis. Once these youth receive their HIV diagnosis, they must contend with adjusting to the news that they are now living with a chronic health condition.

Regrettably, there are no Latino YMSM specific data, however, all studies on Latinos showed that Latinos or immigrants present to clinical care at a later stage in their HIV disease as measured by percent with AIDS or opportunistic infections (OIs), lower CD4 cell count, or faster progression to AIDS or death (Althoff et al., 2010; Carabin et al., 2008; Chen, Gallant & Page, 2012; Giordano et al, 2010; Kelly, Hernandez-Ramos, Franco-Paredes & del Rio, 2007; Levy et al., 2007; Schwarz et al., 2007). In a national clinical trial study for ARV naıve patients, Hispanics were more likely to progress to AIDS or death in unadjusted analysis, although this association disappeared after adjustment for baseline CD4 count and prior AIDS diagnosis (Giordano et al., 2010).

1.1.1.2 Public Health Officials Encourage Efforts to Increase Testing

In 2006, the CDC issued revised recommendations for HIV testing with the goals of increasing HIV screening, fostering earlier detection of HIV infection, reducing perinatal transmission of HIV, and linking those with unrecognized HIV infection into clinical care (CDC, 2006). These recommendations include routine screening for HIV infection among all patients aged 13-64 with an "opt-out" option rather than signed informed consent, regular and repeated (at least annually) screening for persons likely to be at high risk for HIV, and the provision of test results either in person or by phone in order to facilitate notification. Furthermore, these recommendations highlight the importance of linkage to medical care as an essential component of increased HIV screening (CDC, 2006). In fact, several studies have demonstrated that without linkage to care, HIV screening offers little benefit to the patient (Paltiel et al., 2005; Walensky et al., 2005; Sanders et al., 2005). Cost-effectiveness models are quite sensitive to assumptions about receipt of appropriate clinical care since savings associated with screening rely on clinical services and therapeutics to ameliorate associated conditions, delay disease progression, and prevent secondary HIV transmission (Walensky et al., 2005). In this vein, two major initiatives to increase testing and linkage to care among youth are currently underway through the ATN – ATN 093 and ATN 096. ATN 093 is a CDC-NICHD collaboration that aims to link HIV-infected youth identified by local health department with HIV care at ATN medical centers. ATN 096, funded through NICHD and National Institutes of Heath (NIH) Office on AIDS Research (OAR), aims to compare venue testing and social network methods to identify HIV infected Latino youth. The combination of these two projects along with the CDC push for routine screening will lead to an increase in HIV diagnoses among young people, who will then need to be linked to care.

1.1.1.3 Newly Diagnosed Youth Must Engage in Care to Improve Medical Outcomes and Decrease Public Health Risks

Up to one-quarter of HIV-infected individuals in the U.S. are unaware of their status and almost half of patients will undergo testing so late in the course of their HIV disease that they will receive an AIDS

diagnosis within one year (Fleming et al., 2002; CDC, 2003). National studies show that 17% to 29% of HIV-infected persons who have received results and post-test counseling fail to receive care within six months of diagnosis (Turner et al., 2000). Youth may be especially likely to delay or forgo care because of individual characteristics (e.g., stigma and shame, rejection of the diagnosis, low educational achievement, untreated psychosis, depression, substance abuse), family characteristics (lack of health care insurance, family dysfunction, past and current neglect/abuse), and health care system characteristics (e.g., costs to patients, services available, access, efficiency, "youth-unfriendly" staff and services, and immigration or foreign born status) (Turner et al., 2000; Chen, Gallant & Page, 2012). Furthermore, racial and ethnic minorities experience greater delays in entering HIV care (Turner et al., 2000; Samet et al., 1998) and are less likely to receive appropriate care and treatment for HIV (Conviser & Pounds, 2002; Giordano et al., 2005; Halkitis, Parsons, Wolitski & Remien, 2003; Shapiro et al., 1999). It has been reported that young adults have poorer rates of retention in care than older adults, indicating that young adults are more at risk for being lost to follow-up (Ashman, Conviser & Pounds, 2002; Naar-King et al., 2007; Rotheram-Borus, 1997). Although rates of linkage to care among adolescents have not been published, among newly diagnosed adults it is estimated that 20%–40% of HIV-infected individuals fail to attend a clinic visit within three to six months after receiving their HIV diagnosis (Mugavaro et al., 2007).

Patients not engaged in care risk *poorer medical outcomes* since they are less likely to receive ARV therapy, more likely to develop viral resistance, and less likely to achieve viral suppression (Heckman, Catz, Heckman, Miller & Kalichman, 2004). A recent study by Giordano and colleagues (2007) of 2,619 HIV-infected men in the VA system who were followed for over 4 years found that participants with poor retention in care had poorer survival rates, less improvement in CD4 counts, and less reduction in viral load. Another study by Mugavero and colleagues (2007) examined the relationship between missed clinic visits and mortality after initial linkage to outpatient care. Mortality rates in the missed visits group were 2.3 per 100 patient-years versus 1.0 per 100 patient-years in the no-missed visits group – a statistically significant increased risk of mortality. The authors from both of these studies contend that there is a dose-response relationship between medical visits and reduced mortality (Giordano et al., 2007), as well as appointment adherence and virologic response (Mugavero, 2008). In a recent study by Hall and colleagues (2012) of 100,375 people living with HIV in the U.S., 45% had greater than 2 care visits at least 3 months apart. Compared with persons diagnosed with HIV aged 25-64, the percentage established in care was lower among younger (12-24 years) and older persons (over 65 years) diagnosed with HIV. Among the 5,136 persons diagnosed in 2008 and alive within 12 months of diagnosis, 41.6% had a suppressed viral load within 12 months of diagnosis, with the mean number of months from diagnosis to viral suppression being 4.8 months, this relationship was stronger among those in care. Implementation of effective interventions for care engagement is necessary to raise the percentage of people living with HIV/AIDS (PLWH) in continuous care to reach the quality care necessary for viral suppression.

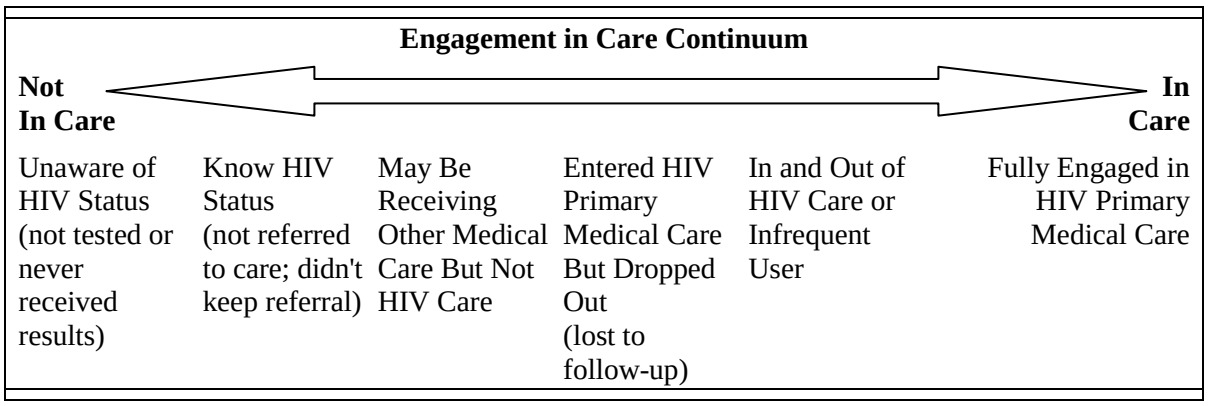
Care engagement is also an opportunity for secondary prevention (i.e., prevention for positives), since studies show that post-diagnosis, men and women in all exposure categories continue to engage in unprotected sex during 33% of their sexual encounters (McGowan et al., 2004; Kalichman, Rompa, Austin, Luke & DiFonzo, 2001, Kalichman & Rompa, 2000; Erbelding, Stanton, Quinn & Rompalo, 2000). Engagement in care provides an opportunity to *decrease viral transmission* through risk reduction counseling and treatment to reduce viral load (Coleman, Rajabin, Cabral, Bradford & Tobias, 2009). Supporting youth who are newly diagnosed with HIV so as to reduce the likelihood that they will transmit the virus to their sexual partners is a major public health opportunity, as these youth may have elevated levels of viral load due to the proximity to their sero-conversion event (and subsequent hypervirimia) or non-adherence to medical care. Recent results from the Health Resources and Services Administration (HRSA)-funded, multi-site Targeted HIV Outreach Initiative demonstrate that people newly diagnosed with HIV and engaged in care had a marked reduction in sexual risk behavior over time. Furthermore, those who had between 1-3 monthly visits were more likely to sustain a reduction in sexual risk behavior

at both 6 and 12-month follow-up (Coleman et al., 2009). Similar results were found in the Antiretroviral Treatment and Access Study (ARTAS) which found that HIV-positive participants who were seen by an HIV care provider at least three times in the previous six months were twice as likely to have abstained from unprotected sex with an HIV-negative or unknown status partner in the preceding month (Metsch et al., 2008). These studies support the importance of engagement in HIV care to reduce sexual risk behavior.

1.1.1.4 Defining Engagement in Care for HIV+ Youth

What constitutes "engagement in care?" HRSA conceptualizes engagement as a spectrum of patient care that ranges from initial diagnosis to full engagement in care (Figure 1). On this continuum, patients can move in both directions across the spectrum (Cheever, 2007).

Figure 1.



"Care" is often difficult to define in a way that provides a sufficiently delimited concept to usefully guide research but recognizes the breadth of needs for infected persons. The proposed study is built from the idea that screening positive for HIV must be associated with specific types of professional, specialized health services to monitor HIV disease status and manage HIV-related medications. These types of services are usually provided within health care delivery units called clinics. Current standards of care stress the importance of medical assessment of HIV disease, including a general assessment of physical and mental health status, identification and treatment of other health problems, provision of appropriate immunizations and preventive care, and assessment of CD4 counts and HIV viral load (Aberg et al., 2004). Widely accepted treatment guidelines from the U.S. Department of Health and Human Services (DHHS, 2011) have long recommended that HIV-infected patients be seen for evaluation at least once every three to six months. In clinically stable patients with suppressed viral load, CD4 count can be monitored every 6 to 12 months. However, studies have also shown that those who are retained in care and seen more frequently demonstrate better survival rates (Giordano et al., 2007).

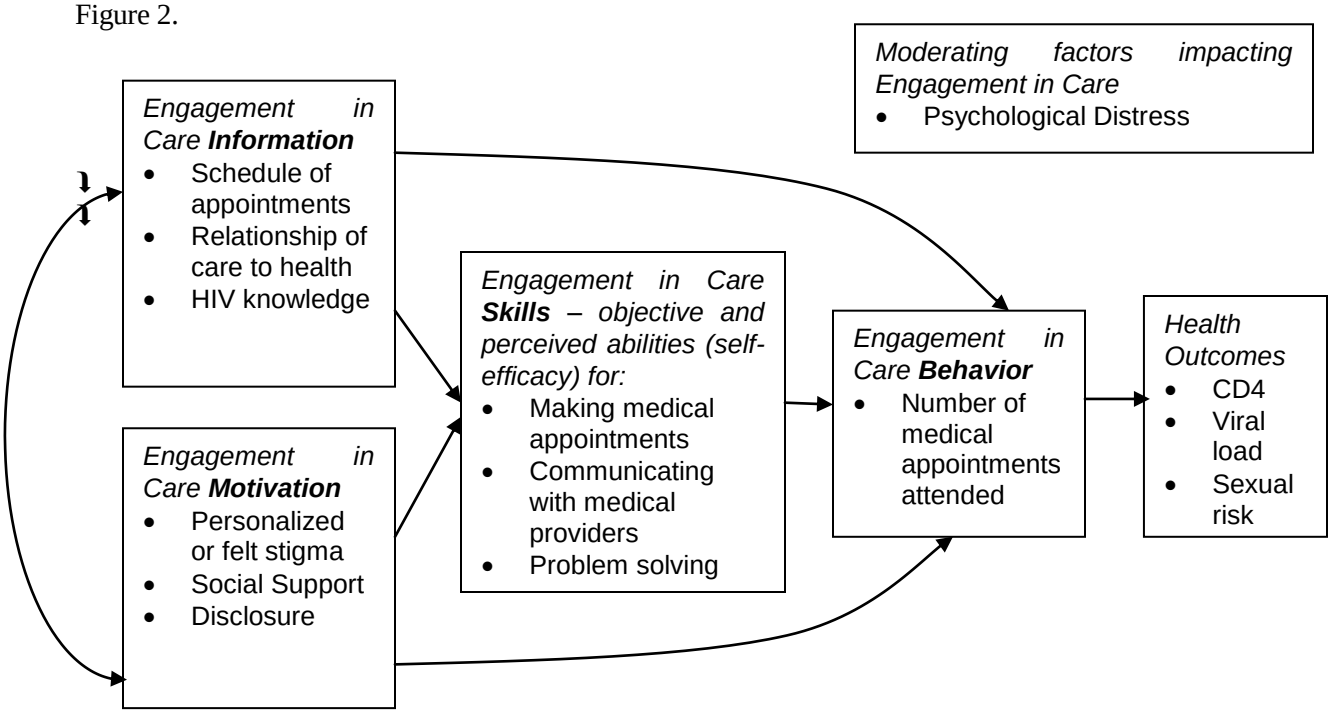
1.1.1.5 Theoretical Foundation

The Project ACCEPT intervention is based on the disability-stress-coping model (Wallander & Varni, 1995) and incorporates information and skills-building activities guided by both social cognitive theory (Bandura, 1986) and the Information-Motivation-Behavioral (IMB) Skills Model (Fisher & Fisher, 1992). Wallander and Varni's (1992) Disability-Stress-Coping Model of adjustment applies a risk and resistance framework to stress and coping theory and does so specifically for children and adolescents living with a chronic illness. The model proposes that risk and resistance factors interact to impact an adolescent's adaptation to his/her chronic illness and/or disability. In this model, risk factors include a) disease/disability parameters, b) functional independence, and c) psychosocial stress. Resistance factors

fall into three categories: a) intra-personal (e.g., competence), b) socioecological (e.g., peers, family, and health care providers), and c) stress-processing (e.g., coping strategies). This model purports that as modifiable risk and resistance factors are identified in empirical research studies, they then provide heuristic guidance for new treatment interventions for adolescents living with chronic illnesses and disability (Wallander & Varni, 1992).

Many HIV-related intervention approaches (both prevention and treatment/adherence) have been guided by the IMB Skills Model developed by Jeff and Bill Fisher (1992). According to the IMB model, HIV behavior change results from the joint function of three critical components: the accurate information about HIV-related health behaviors, the motivation to perform health behaviors, and the self-efficacy and behavioral skills necessary to perform the behaviors. The IMB model, primarily validated for risk behaviors, has recently demonstrated empirical support to predict highly active antiretroviral therapy (HAART) adherence (Fisher, Fisher, Amico & Harman, 2006 – Figure 2). Applying the IMB model of adherence (Fisher, Fisher, Amico & Harman, 2006) to engagement in care, we propose an intervention (Project ACCEPT) that targets each of the IMB components as compared to a comparison intervention that includes the Information component but not the Motivation and Behavioral Skills components (HEALTH). The following sections describe the IMB components that have a demonstrated relationship to engagement in care.

Figure 2.



Information and Engagement in Care

Health-related knowledge is an important factor in predicting an individual's ability to manage a chronic health condition, utilize appropriate medical services, retain treatment instructions, and adhere to medical regimens (Kalichman, Ramachandran & Catz, 1999; Baker, Parker, Williams & Clark, 1998; Davis et al., 1996). HIV positive individuals who are not knowledgeable about HIV disease, treatment options, and services are less likely to engage in health care (Cheever, 2007; Tobias, Cunningham, Cunningham & Pounds, 2007; Rumptz et al., 2007). Kalichman and Rompa (2000) found that HIV-infected people with lower health literacy had poorer knowledge of their own HIV-related health status, more negative perceptions about the health care system, and more difficulties accessing HIV care. Rumptz and colleagues (2007) reported that beliefs regarding the mistrust in the medical health system, impact of treatment side effects, HIV as an incurable disease and perceptions of not being sick enough are significantly associated

with decreased degree of engagement. Thus, people living with HIV that had less knowledge and held negative beliefs about HIV were more likely to be disengaged with their healthcare. Ulett and colleagues (2009) extend these findings to call attention to educating younger people living with HIV about the importance of engagement in care.

Motivation and Engagement in Care

While advances in medical technology have increased the effectiveness of treatment for HIV, these advances have also heightened the importance of adherence to medical healthcare in general. An ever increasing body of literature supports the idea that perceived and internalized stigma have a direct negative impact on an HIV-positive individual's engagement in healthcare (Rao, Kekwaletswe, Hosek, Martinez & Rodriquez, 2007; Waite, Paasche-Orlow, Rintamaki, Davis & Wolf, 2008; Wolitski, Pals, Kidder, Courtenay-Quirk & Hotgrave, 2008). Stigma has been shown to be associated with individuals not accessing services and not taking ARV medication (Tobias, Cunningham, Cunningham & Pounds, 2007). For HIV-positive youth, the issues surrounding receiving medical care are compounded by the fear of social stigma, isolation, and rejection by family and friends when they disclose their HIV status (Rao, Kekwaletswe, Hosek, Martinez & Rodriquez, 2007; Hosek, Harper, & Domanico, 2005). Naar-King and colleagues (2007) found that people newly diagnosed with HIV who reported experiencing stigma were less likely to be retained in medical care.

While social support may buffer stress, influence affective states, and/or change behaviors (Cohen, 1988), it also has the potential for negative influences on chronically ill individuals, depending on the severity of their illness and the complexity of their medication regimen (Martin, Davis, Baron, Suls & Blanchard, 1994; Penninx et al., 1998). Extensive research exists on the role of social support and patient adherence to medical treatment and the complex relationship between the two (DiMatteo, 2004). Social support also indirectly affects lifestyle or health behavior changes that can improve health maintenance thus impacting adherence to treatment (Cohen, 1988; DiMatteo & Hays, 1981). Non-supportive social networks may inhibit change in health habits, including engagement into care, by introducing additional stressors that can compromise attitudes and behaviors necessary for medical adherence (Kaplan & Hartwell, 1987). For example, Rao and colleagues (2007) found that discrimination by family and friends lead HIV-infected youth to skip doses of medication.

Psychological Distress and Engagement in Care

A large body of literature has documented that psychological distress and mental illness have an important impact on medical care in general and HIV medical care in particular (Joyce, Chan, Orlando, & Burnam, 2005; Palacio, Shiboski, Yelin, Hessol & Greenblatt, 1999; Samet et al, 1998). Within the context of HIV care, mental health services have the potential to increase connection and engagement in care (Reece, 2003). Recently, Basta, Shacham and Reece (2008) found a significant relationship between psychological distress and level of HIV care engagement, with "highly engaged" individuals having significantly lower levels of depression than those that were "moderately" or "minimally" engaged. Several studies have also demonstrated the relationship between psychological distress to appointment and medication adherence. In a qualitative study of HIV-infected adolescents, Hosek, Harper and Domanico (2000) found that adolescents who expressed hopelessness about their future due to HIV also reported difficulties with attending appointments and taking their ARV medications. More recently, Naar-King and colleagues (2006) found that psychological distress was a significant predictor of non-adherence among HIV-positive youth. Therefore, the affective responses to an HIV diagnosis may interfere with an individual's willingness or ability to engage in care.

1.1.1.6 Existing Interventions

There are no existing interventions that focus on improving engagement in care among HIV-positive youth. There are only a few intervention studies for HIV-positive youth cited in the literature and none

with a primary focus on engagement in care or newly diagnosed youth. Thus, it is important to review the existing intervention studies among HIV-infected youth in the areas of risk reduction and medication adherence, as well as studies of engagement in care among HIV-infected adults.

Risk Reduction Interventions for HIV-Positive Youth

Rotheram-Borus and colleagues (2001) developed a 23-session group-based intervention for use with behaviorally HIV-infected youth. *TLC* (Together Learning Choices, previously referred to as Teens Linked to Care) is a small-group intervention designed for youth and young adults living with HIV. *TLC* consists of 2 modules: *Stay Healthy* and *Act Safe*. The *Stay Healthy* module consists of 12 sessions to promote positive health behaviors. The *Act Safe* module consists of 11 sessions to increase self-protection and other-protection motivation to change behavior and to reduce substance use and unprotected sex acts. In all, 257 youth participated in the intervention trial (mean age=21; 72% male, 64% ethnic minority). *TLC* participants were significantly more likely to report no sexual risk pattern and significantly lower percentages of unprotected vaginal and anal sex acts than the control group ($p < .05$) at three months after the *Act Safe* module. Youth who participated in this intervention, as compared to those in the control condition, reported increased social support, positive lifestyle changes, and active coping. It is important to note, however, that over 25% of participants attended less than half of the required sessions (Rotheram-Borus et al., 2001). Additionally, the researchers suggest the need to identify alternative formats for delivering interventions other than group-only (2001).

CLEAR (Choosing Life: Empowerment, Actions, Results), an offshoot of *TLC*, is a three-module intervention that is delivered in individual sessions to substance-using young people living with HIV (Rotheram-Borus et al., 2004). Each of the three modules is comprised of six sessions that focus on different target behaviors. Module 1 focuses on improving youths' physical health, including the use of and adherence to ARV medication, implementing new daily routines to stay healthy, and coping with their serostatus. Module 2 aims to reduce unprotected sex acts and substance use through the identification of situations that elicit risky behavior. Module 3 aims to reduce emotional distress and to increase quality of life of participants. One hundred and seventy-five youth (78% male, median age = 23) living with HIV participated in the efficacy trial. At 15 months post baseline, participants who received the *CLEAR* intervention reported significantly greater increases in the proportion of protected sex acts with all sex partners ($p < 0.01$) and proportion of protected sex acts with HIV seronegative partners ($p < 0.05$) compared to wait-list control participants. However, other targeted outcomes, including substance use, HIV medication adherence, health behaviors, and emotional distress, were not significantly improved by the intervention.

More recently, Markham, Shegog and colleagues (2009, 2011) completed a pilot test of "+CLICK", an individual, web-based application designed to enhance sexual risk reduction skills among perinatally-infected youth. ''+CLICK'' targets four behaviors: choosing not to have sex, disclosing HIV status to a potential sex partner, using condoms correctly and consistently, and using an effective method of birth control along with condoms. Thirty-two HIV-positive youth (mean age = 17.8, 62.5% female, 68.8% African-American) completed the pilot study. Short-term psychosocial outcomes indicated a significant increase in condom use self-efficacy ($p=0.008$) and positive trends toward importance ($p=0.067$) and self-efficacy ($p=0.071$) for waiting before having sex. Acceptability and feasibility ratings were high.

Adherence Interventions for HIV-Positive Youth

Of the several published adherence studies currently in the literature, several utilized directly observed therapy (DOT; Purdy et al., 2008; Parsons et al., 2006; Glickman, Walsh, Valkenburg, Mangat & Marcinak, 2007) and one utilized medication scheduling (i.e., reduction to once-daily dosing) as the intervention. One behavioral counseling intervention, The Therapeutic Regimens Enhancing Adherence in Teens (TREAT) program, (Rogers, Miller, Murphy, Tanney & Fortune, 2001) evaluated an eight-week program involving medication education via videotapes, booklets, and audiotapes. Only 18 out of 112

participants completed the program. Of those that completed, two-thirds initiated ARV therapy and half self-reported adherence "most" to "all of the time" (Rogers, Miller, Murphy, Tanney & Fortune, 2001). Lyon and colleagues (2003) used a family group approach by recruiting 30 pairs of HIV-infected youth and a family member to engage in 12 weeks of education sessions in a group psychotherapy format. Ninety-one percent of participants reported increased adherence and most showed improvement in CD4 counts (2003). Finally, Naar-King and colleagues (2009) tested Healthy Choices, a four-session motivational enhancement intervention that combined motivational interviewing (MI) with cognitive-behavioral strategies such as decisional balance and goal setting to improve adherence. The intervention did not significantly improve viral load immediately post treatment, but improvements in viral load were significant at six months post baseline compared to multidisciplinary specialty care alone. Only 50% of youth attended all sessions and changes in viral load were not maintained at nine months (2009).

Engagement in Care Interventions for HIV-Positive Adults

While no intervention studies targeting engagement in care for newly diagnosed HIV-infected youth have been published, a recent study evaluated the efficacy of a case management intervention (ARTAS) aimed at linking newly diagnosed HIV-infected adults into care (Gardner et al., 2005). In this study, participants recently diagnosed with HIV were randomized to either standard of care passive referral or the case management intervention. This manualized intervention, modeled on a strengths-based case management approach (Saleebey, 1997), involved assignment to a case manager and up to five case management contacts per client. Results showed that a significantly higher proportion of case-managed participants enrolled in medical care within six months of the intervention. Additionally, those participants that received the intervention within six months of their diagnosis were more likely to have made multiple visits to HIV medical care providers (Gardner et al., 2005).

Another intervention, The Outreach Initiative, aimed to improve retention in care and reduce viral loads among adults (mean age = 30) newly diagnosed with HIV (Naar-King et al., 2007). The program offered intensive outreach contact (approximately 5 hours per month) that offered HIV education and support, assistance addressing stigma, and advocacy to address financial and structural barriers. Results show that almost all participants (92%) had an HIV care appointment in the 6 months post-enrollment and 85% had an appointment between 6 and 12 months post-enrollment. Furthermore, viral load at 6 and 12 months post-enrollment was significantly decreased from baseline (2007).

1.1.2 Preliminary Studies

The proposed study is a continuation of the intervention development research that has been completed in two previous studies conducted by the investigative team and funded through the ATN: 1) ATN 055 which was an exploratory, qualitative investigation of the challenges, strengths, and needed areas of support associated with receiving an HIV diagnosis among youth living with HIV in order to ultimately improve engagement in healthcare; and 2) ATN 068 which completed intervention development, produced an intervention manual, trained interventionists and peer facilitators to implement the manualized intervention (Project ACCEPT), and evaluated the intervention for feasibility, acceptability, and initial effect sizes. The intervention addressed a range of issues that impact engagement in care for youth living with HIV, including stigma, disclosure, healthy relationships, substance use, and future life planning.

1.1.2.1 ATN 055: Assessing Needs of Youth Newly Diagnosed with HIV and Intervention Development

In ATN 055, information was elicited from individual interviews with medical and mental health providers, as well as case managers, regarding the intervention needs of youth (ages 16-24) newly diagnosed with HIV. Focus groups were then conducted with HIV-positive youth from three ATN sites (Chicago, New York, and Puerto Rico) to identify the challenges, strengths, and needed areas of

support/assistance associated with receiving an HIV diagnosis in order to ultimately improve engagement in healthcare. Qualitative data from these interviews and focus groups were analyzed and used to guide the development of an intervention outline.

ATN 055: Themes from Provider Interviews

Fourteen clinical providers, 13 mental health providers and 13 case managers participated in the interviews, representing 14 of the 15 ATN sites. Providers were asked to discuss the difficult issues they perceive youth have to deal with during the first six months after receiving an HIV diagnosis. Themes that emerged from the interviews are as follows (Hosek, Harper, Lemos, & Martinez, 2008): 1) *Mental Health Issues*. Providers reported complicated psychological and social impact on the youths' lives before and after the diagnosis—many HIV-positive youth have underlying psychological stressors prior to the diagnosis and addressing these concerns is of utmost importance when dealing with newly diagnosed youth. Providers also cited the difficulty of having to work with dual or even triple diagnoses (i.e., HIV, substance abuse and mental health); 2) *Developmental Issues*. Providers discussed the importance of addressing the developmental issues of newly diagnosed youth who are struggling with an HIV diagnosis and normal developmental issues simultaneously. Of particular importance were sexual identity, independence/autonomy, and HIV identity; 3) *Health Management Issues*. All providers felt that attention to health management was important for newly diagnosed youth who may need assistance in learning to navigate health care systems and arranging medical care. Providers reported that while many newly diagnosed youth would not be eligible for medications yet, an intervention should begin to prepare them for medication management; 4) *Social Support Issues*. Providers reported that many youth come from troubled homes and have no immediate source of social support. They felt that an intervention should help to build social support on multiple levels. Providers discussed the importance of addressing youth's concerns about the process of disclosure, expectations about disclosure and moving forward after disclosure.

ATN 055: Focus Groups/Individual Interviews

Four focus groups (N=16) and 14 individual interviews were conducted with a total of 30 HIV-positive participants (mean age = 21, 53% female, 53% Hispanic, 40% African American) at three ATN sites (Bronx, Chicago, Puerto Rico). All participants had been diagnosed with HIV within the past two years (average time since diagnosis = 16 months). Qualitative data analysis provided us with insight into the challenges that newly diagnosed youth face. Youth reported that the 12 months after receiving an HIV diagnosis was a critical period for psychological adjustment. When asked to identify the most difficult issues during those first 12 months, several critical areas of stress were identified (Hosek, Harper, Lemos & Martinez, 2008): 1) *Mental Health*. Many of the youth described the onset of depressive or anxious symptoms after receiving the HIV diagnosis. Other participants reported feelings of anger directed at themselves as well as the person that infected them. Participants also experienced a drop in self-esteem and increased negative self-worth after receiving the diagnosis. The youth reported developing a fatalistic mentality which interfered with their medical care or treatment. Some youth reported not seeking medical care for months after receiving the diagnosis or completely avoiding anything that had to do with HIV; 2) *Disclosure*. Among the most critical stressors that youth identified in the months following the diagnosis were concerns involving disclosure of their HIV status to family, friends and significant others. The reasons most commonly cited by the youth for fear of disclosing to family members were fear of rejection or of being physically thrown out of their house by their family members. Another concern for many young men was that of dual disclosure, because disclosing their HIV status meant they also had to disclose the fact that they are gay. Among the youth taking medication, there was a profound fear that the family members would identify the medication as HIV-related medication. Additional apprehension was that their daily routine was impacted by the frequent medical visits and/or calls from the clinic during the initial period; 3) *Lack of HIV/AIDS Education*. Youth discussed their beliefs about HIV being a death sentence. They reported hearing misinformation from family, friends, and community members. Youth also discussed the fear of accidentally infecting family members. A simple cut or simply forgetting to

pick up after themselves could trigger a dramatic reaction from the participants who had small children or who were living with family members who were unaware of their status. The fear of infecting others was often reinforced by the family's reaction to other HIV-positive family members, such as keeping separate toothpaste and disposable utensils; 4) *Time Management.* Participants reported difficulty adjusting to their medical schedule including taking medications, attending doctor's visits and coming into the clinic frequently for laboratory tests. Concerns revolved around fitting these routines into their life. Many were concerned with how they could attend school or work while having to get to the clinics. They also had to learn to plan when they would take their medications so the medications would not interfere with their social life; 5) *Dating & Relationship Concerns*. An apprehension of romantic relationships was expressed by many of the participants. Some youth reported that they purposely avoided relationships or even broke off their relationships post-diagnosis. They spoke of the anger they felt toward the person that infected them and how this anger led to further mistrust about being in a relationship. Some youth also reported a diminished sex drive. There was also concern regarding partner notification. One participant felt particularly angry about having to tell partners about her HIV status because she felt it was unfair that she did not hear that from the person who infected her; 6) *Gender-Specific Concerns*. Male participants often discussed sexual orientation identity as one of the most difficult issues they had to deal with during the first 12 months. For some youth, the diagnosis meant that they had to come to terms with their sexual orientation identity. The concerns that female participants voiced involved having children. Women expressed hesitation toward pregnancy because they feared the child would be HIV positive. Also, among women with and without children, there was an ongoing anxiety about being alive for their children in the future. Additionally, they were concerned about how and when they would disclose their status to their own children.

In conclusion, data from both the provider and youth interviews supported the need for services targeting newly diagnosed youth. The data suggested that interventions should be supportive in offering help for improved psychological adjustment as well as assistance with disclosure. For the vast majority of youth living with HIV, these critical psychosocial issues are addressed through engagement in care since it is through connections with care facilities that youth gain access to medical providers, mental health providers, case managers and other members of a comprehensive care team. Providers felt that the intervention should be fairly intensive and youth suggested that the format include both individual and group sessions. Many youth also expressed the desire to include interactions with a HIV-positive peer. Finally, youth stressed the importance of making the intervention fun and interactive. From the ATN 055 data, the theoretical model, and the literature, an intervention outline involving both individual and group sessions was developed.

1.1.2.2 ATN 068: Acceptability, Feasibility, and Initial Effect Sizes

In ATN 068, intervention development was completed, an intervention manual was produced, interventionists and peer facilitators were trained, the manualized intervention at four ATN sites (Chicago, New York, Memphis, Miami) was implemented, feasibility and acceptability were assessed, and initial effect sizes were calculated. The manualized intervention, Project ACCEPT, combined three individual and nine group sessions that aimed at addressing a range of issues that impact engagement in care for youth living with HIV, including stigma, disclosure, healthy relationships, substance use, and future life planning. All Project ACCEPT sessions were co-facilitated by a team of one mental health professional and one HIV-positive peer facilitator.

A total of 50 participants (28 male, 22 female; mean age = 19.65) diagnosed with HIV for 15 months or less (mean= 8.36; range 1-15) were enrolled into the Project ACCEPT study (ATN 068). The majority of participants (78%) were African American, 20% Hispanic, and 5% White. Of the females, 96% identified as straight and 97% of males identified as gay or bisexual. Session attendance for each of the sessions was calculated as an indicator of feasibility. Eighty-four percent (84%) of participants attended 6 or more

group sessions and 30% of participants completed all 9 group sessions. 100% of participants attended the first 2 individual sessions and 86% completed the final individual session. There was a minimal 4% attrition rate over the entire study. Client satisfaction questionnaires indicated high levels of satisfaction with the intervention program. Overall, 98% of the respondents rated the quality of the intervention as excellent or good. 100% of respondents felt they were able to get the kind of services they wanted and that almost or all of their needs were met with the program. In addition, 98% of participants indicated that the program helped them deal more effectively with their problems. In post-intervention focus groups, participants reported that they enjoyed each of the topics covered and that the sessions were a) educational, b) instructional, and c) fun.

The intention of exploratory quantitative analysis for ATN 068 was to look for trends in the data. Furthermore, the small sample size plus the large variability within measures gave us low power to detect statistical differences within sample. Despite these limitations, analysis of the data revealed promising intervention effects in the following areas:

a) HIV/STD Knowledge (Diclemente,1994)
Knowledge related to HIV and STDs increased substantially immediately post-intervention (M=12.33, SD=2.50), with an overall effect size of d=.42. This knowledge increase was sustained at the three-month follow-up, with an overall effect size of d=.52 (M=12.61, SD=2.66) when compared to baseline scores.

b) Social Support (Seidman, et al.1995)
Peer support increased from baseline (M=12.52, SD=3.33) to post-intervention (M=13.67, SD=3.28), demonstrating an effect size of d=.35. At the three-month follow-up, overall peer support maintained the increase from baseline, with an effect size of d=.22 (M=13.2, SD=2.95). Increases were also observed in formal support (i.e., from medical providers), with mean scores increasing from baseline (M=16.51, SD=4.04) to post-intervention (M=17.41, SD=5.04), with an effect size of d=0.20. Overall mean scores dipped slightly at the three-month follow-up (M=16.99, SD=4.25), but a positive effect size was maintained (d=.12).

c) HIV Related Personalized Stigma (Berger, Ferrans, & Lashley, 2001)
Personalized stigma related to HIV status improved post-intervention (M=51.05, SD=11.23), with an effect size of d=.11. Observed reductions in personalized stigma did not hold through the three-month follow-up, however.

d) Self-efficacy for Disclosure (Lux & Petosa, 1994)
When assessing for self-efficacy related to disclosure of HIV-positive status (range=6-30, with higher scores related to higher self-efficacy for disclosure), females experienced an increase from baseline (M=14.57, SD=7.98) to post-intervention (M=15.90, SD=7.19), representing an effect size of d=.18. For males, baseline scores started at a higher level (M=19.24, SD=8.1) than females, but also demonstrated an increase following the intervention (M=20.06, SD=7.64), with an effect size of d=.11. Overall increases were maintained at the three-month post-intervention follow-up, although effect sizes were slightly attenuated (d=.07 and .05 for females and males, respectively).

e) Depressive Symptoms (Center for Epidemiologic Studies Depression Scale (CES-D)), (Radloff, 1977)
Utilizing a 0-60 point scale to assess depressive symptoms (with higher scores indicating more symptoms), 32% of youth met or exceeded the clinical cutoff for depression at baseline (23% of females and 42% of males). Immediately following the group intervention, depressive symptoms dropped to a mean score of 14.21 (SD=10.31), an effect size of .39. At the three-month follow-up, participants (M=14.58, SD=12.34) maintained an overall decrease in symptoms when compared to their baseline scores, with an effect size of d=.33.

f) Engagement in Care
The number of participants on medication increased by 42% from baseline (n=8) to post-intervention (n=12), and increased even further from baseline to the three-month follow-up (67% increase, n=20). The overall number of missed doctor's appointments decreased at both post-intervention and three-month follow-up, with effect sizes of d=.30 and .15, respectively. Clinical appointment forms completed by site staff revealed that participants had an average of 2.42 (SD=1.99) medical visits during the 12-week intervention period, of which 75% were scheduled medical visits. Further, participants expressed increasing levels of comfort with asking their doctor questions ("very comfortable" asking questions = 76%, 85%, and 87% at baseline, post-intervention, and follow-up). In addition to the quantitative data, post-intervention focus group data from staff and participants supported participant's sustained engagement in care. For example, staff discussed marked improvements in youth's perceptions regarding the role of health care professionals' ability to influence positive health outcomes. Youth also expressed improvements in motivation to seek-out information and consult with their health care providers on health-related issues.

1.1.2.3 Finalizing Project ACCEPT

Based on the ATN 068 feasibility data, edits have been made to the Project ACCEPT intervention manual and the number of group sessions was decreased from nine to six. In ATN 068, while only 30% of participants completed all nine group sessions, 84% of participants attended six or more group sessions. In post-intervention focus groups, participants suggested that the number of sessions could be decreased by eliminating specific components that they felt were not immediately relevant to newly diagnosed youth. The participants suggested deemphasizing components of community advocacy *(Session 8 – public policy overview, community connections, community issues, and advocacy*), specific components of the future planning session *(Session 9 – college applications, Job Corps, & vocational schools)* and spirituality *(Session 5).* Youth focus group participants suggested that these components could be offered through referrals or as part of the individual action plan in the last individual session. Although the youth felt that community advocacy was an important component for HIV-positive youth, they felt that it did not need to be addressed during the first year following diagnosis.

1.2 Rationale

While the aforementioned studies offer valuable information about interventions for HIV-positive youth, none have focused on engaging newly diagnosed youth in care. The CDC and other governmental bodies have been increasing efforts to test youth and identify those who are living with HIV so they can receive much needed medical and psychosocial support. When youth living with HIV are engaged in medical care, they not only have improved physical and mental health outcomes, but they also decrease their participation in health risk behaviors which may further the spread of the virus to others. Improving engagement in care is especially critical for those youth who are newly diagnosed with HIV so these youth can establish sustainable healthy patterns of behavior.

Prior interventions for adolescents and young adults living with HIV have not been developed to address the many needs of young people living with HIV in order to improve their engagement in care, as well as other medical health outcomes. Strong evidence exists about the difficulty youth have adjusting to a chronic illness, particularly in the areas of psychological functioning and medical management (Sayer, Hauser, Jacobson, Willett & Cole, 1995; Wallander & Thompson, 1995; Lavigne & Faier-Routman, 1992; Gavaghan & Roach, 1987). For adolescents and young adults living with HIV, unique difficulties may arise, due to the highly stigmatized nature of their illness, which will interfere with their ability to adequately engage in care (Brown, Lourie & Pao, 2000). This struggle can result in negative medical (i.e., poor adherence), psychological, and public health outcomes (Hosek, Harper & Domanico, 2005; Murphy

et al., 2001a). Thus interventions for youth who are newly diagnosed with HIV need to address an array of issues that may negatively impact engagement in care.

Such interventions aimed at increasing engagement in care should be based in theory, and grounded in prior research with youth who are living with HIV. Although the IMB model was primarily validated for HIV-related risk behaviors, it has recently demonstrated empirical support to predict HAART adherence and will be applied to engagement in care behaviors in the current study. Prior intervention development work by the research team has incorporated elements of the IMB model with findings from qualitative work with adolescents/young adults newly diagnosed with HIV to develop the Project ACCEPT intervention which is focused on improving psychosocial adjustment to an HIV diagnosis and engagement in care. The current study aims to fill the gap in the existing literature by testing an intervention that was developed for youth newly diagnosed with HIV – Project ACCEPT – as compared to a health education comparison condition (HEALTH). Findings from this study will offer valuable information that will assist in improving the health of a growing population of young people living with HIV in the U.S., and help to decrease the spread of the virus to other people.

2.0 STUDY AIMS AND HYPOTHESES

2.1 Primary Aim

- To conduct a randomized controlled trial to examine the efficacy of Project ACCEPT compared with an attention-controlled health education comparison condition (HEALTH). The goals of the intervention are to improve engagement in care, decrease psychosocial barriers to care, and decrease sexual risk for youth newly diagnosed with HIV.

2.2 Exploratory Aim

- To explore the relationship between HIV biomarkers (i.e., CD4 and viral load) and participants' level of engagement in care.

2.3 Study Hypotheses

- *Hypothesis 1a:* Participants in Project ACCEPT will demonstrate greater engagement in care, as measured by HIV medical appointments and engagement with medical providers, compared to HEALTH participants.

- *Hypothesis 1b:* Participants in Project ACCEPT will show decreases in psychosocial barriers to engagement in care, including improved knowledge, decreased psychological distress, decreased stigma, and increased social support, compared to HEALTH participants.

- *Hypothesis 1c:* Participants in Project ACCEPT will have fewer episodes of unprotected sex and fewer new diagnoses of STDs compared to HEALTH participants.

3.0 STUDY DESIGN

The proposed study is a two-group randomized repeated measures design (baseline and four follow-up points) examining the efficacy of Project ACCEPT to improve engagement in care among youth newly diagnosed with HIV at five AMTUs across the U.S (See Appendix II). The primary outcome is

engagement in care with secondary outcomes of decreased psychosocial barriers to care and decreased sexual risk behavior.

For this trial, an adaptive clinical trial design will be implemented, which is defined as a study that includes a prospectively planned opportunity for modification of one or more specified aspects of the study design and hypotheses based on analysis of data (usually interim data) from participants in the study (Bretz, Koenig, Brannath, Glimm & Posch, 2009). Using this framework, Chen and colleagues (2004) report that analyses of the accumulating study data can be performed in a fully blinded manner or in an un-blinded manner and can occur with or without formal statistical hypothesis testing. An adaptive trial design, enrolling youth in up to three waves, in order to improve the efficiency by potentially decreasing the duration of the trial and enrolling fewer participants (Fitts, 2010) is proposed for this study.

To determine the efficacy of an intervention, Rounsaville and colleagues (2001) strongly recommend that researchers conducting tests of behavioral interventions select an optimum comparison condition. Thus, for this study, an attention placebo control condition, HEALTH, developed specifically for adolescents when testing the efficacy of the Project ÒRÉ intervention (ATN 034 - an HIV/STD primary prevention intervention for urban African American female adolescents (Dolcini, Harper, Boyer, Pollack & the ATN, 2010).) will be modified. HEALTH is focused on general health habits, diet, nutrition, and exercise. Information on alcohol, drugs, HIV and other STDs will be included to meet the ethical responsibility to provide risk reduction information to youth assigned to this condition. HEALTH will include the information component of the IMB model, but not the Motivation and Behavioral Skills components. The modified HEALTH intervention will be parallel in number of sessions and duration to Project ACCEPT.

3.1 Study Population

Youth newly diagnosed with HIV within the past 12 months (+3 months) and aware of their HIV diagnosis that are between the ages of 16 and 24, will be randomized into either Project ACCEPT or HEALTH in up to three waves. Within each condition, participants will be separated by gender. It is expected that not all sites will have female participants in each wave.

3.1.1 Using past 12 months as definition of "newly diagnosed"

Qualitative data collected during ATN 055 (Hosek, Harper, Lemos & Martinez, 2008) demonstrated participants considered the 12 months after receiving an HIV diagnosis as an adjustment period in which participants reported being under enormous emotional stress. Youth reported that the one-year mark post-diagnosis was a milestone after which they no longer considered themselves "newly diagnosed."

3.2 Sample Size

Approximately 240 youth (approximately 180 males, 60 females) will be enrolled in this study over a maximum of three waves. Each of the five sites will enroll approximately 16 participants (12 male and 4 females) into each of three waves for a total of 48 participants per site. Sites may over enroll up to eight males per group per wave. Once the group sessions begin, participants will not be replaced however, should participants prematurely discontinue from the study prior to the start of group sessions, these participants may be replaced.

3.3 Study Randomization, Stratification, or Description of Non-Random Assignment Procedures

3.3.1 Randomization

Random assignment will occur at the baseline visit. Male participants will be randomized in blocks at each participating site into one of two study arms: 1) intervention (Project ACCEPT), or 2) comparison (HEALTH) in a 1:1 ratio. Female participants will be randomized in blocks in a 1:1 ratio at each participant site that has sufficient female youth for both study arms. Sites without sufficient female youth for both study arms, but with at least two female youth, will be randomized to one of the study arms.

Randomization assignments will be performed by the statisticians at the ATN DOC via the ATN website (https://www.atnonline.org). The SC (or designee) will complete an ATN 108 Randomization Worksheet, which contains a series of questions that verify participant eligibility. The SC (or designee) will log on to the ATN website and submit the worksheet information to request randomization. Shortly after the randomization request is submitted, the designated team members will receive a confirmation email of the study arm assignment.

3.3.2 Gender separated groups

The decision to separate groups by gender is based on data gathered from ATN 055 (Hosek, Harper, Lemos & Martinez, 2008) in which participants reported the preference for gender-specific groups in order to allow for a greater sense of comfort while discussing gender-specific topics (e.g., females raised concerns about pregnancy, males raised concerns about sexual orientation). Additionally, post-intervention focus groups revealed that forming gender-separated groups to deal with the aforementioned issues and having gender-matched facilitators and peer facilitator allowed for greater participant engagement and retention in the intervention program.

3.4 Outcome Measures

Most of the primary and secondary endpoints are to be administered by ACASI, and the remainder collected through medical record abstraction.

3.4.1 Primary Study Endpoints

- To improve engagement in care as measured by HIV medical appointments and engagement with medical providers. These endpoints will be measured using the following:
    - Engagement in Care: Medical record review will be used to establish appointment adherence to HIV primary medical care visits in the previous 12 weeks. Medical records are necessary because participants have been found to over self-report visits (Sohler et al., 2009). Appointment adherence will be defined as the number of completed visits divided by the number of scheduled visits in that time frame (Mugavero, 2008). Secondarily, visit constancy (Mugavero et al., 2009) which is the proportion of three-month time intervals with at least one completed clinic visit will also be measured.
    - Engagement with Healthcare Provider (Bakken et al., 2000): The Engagement with Healthcare Provider scale is a 13-item questionnaire developed to rate the nature of patient interactions with their healthcare provider on a 4-point Likert scale. This questionnaire will be administered in the ACASI. (See Appendix IV)
    - HIV Treatment Readiness Measure (Fernandez et al., 2011): The HIV Treatment Readiness Measure (HTRM) was developed to assess adolescent's HIV treatment Readiness in clinical care

settings. The refined HTRM had high internal consistency (α = 0.84). Test–retest reliability using both sum scores and mean scores were high. The HTRM was also highly acceptable and feasible to use in routine clinical practice. Exploratory factor analysis found that a five-factor solution was the best fit; each of the subscales (*Disclosure, Psychosocial Issues, Connection with Care, HIV Medication Beliefs,* and *Alcohol and Drugs*) had good to acceptable alphas and eigenvalues greater than 2.0. (See Appendix XXVI)

- Antiretroviral Medication Adherence: The questionnaire was developed by the Adherence Working Group. The Working Group identified key areas that have been associated with adherence to medication, as well as with non-adherence. Basic questions about adherence from previous International Maternal-Pediatric-Adolescent AIDS Clinical Trials Group (IMPAACT) and ATN studies were reviewed and modified according to recommendations made by Simoni et al. (2006). Items from the IMPAACT adherence assessment that focused on facilitators for and barriers to adherence were used. Subtests are included to assess the perceived relationship with health care providers (Davies et al., 2006) and current stability of housing, as measured by the Pediatric AIDS Clinical Trials Group (PACTG) adherence study. Finally, on a visual analogue scale (VAS) youth will rate from 0% to 100% in the last month how adherent they have been. Both scales will be administered in the ACASI. (See Appendices V and VI)

- Intention to Adhere to HIV Treatment (Nelsen et al., 2012): This 17-item scale measures patients' behavioral intention to adhere to HIV care. Items were chosen to reflect behavioral intention as defined by the Health Action Process Approach to health-seeking behavior. Items reflecting self-reported HIV knowledge were also included after expert panel review. The measure has been validated with HIV positive adults and has good internal consistency for knowledge (Cronbach's a = 0.83) and for intention (Cronbach's a = 0.81). For this study, we will utilize the 10-item intention subscale. (See Appendix XXIII)

- Health Care Utilization Survey: This is a 24-item survey which includes questions regarding participants' current and past use of health care services, reasons for utilization, relationship and level of satisfaction with health care provider, perception of health care providers' knowledge of HIV/AIDS, and adherence to health care appointments. This survey was developed by the Center for Community Health, Semel Institute-Neuropsychiatric Institute of the University of California, Los Angeles. A modified version of this questionnaire will be administered in the ACASI. (See Appendix VII)

3.4.2 Secondary Study Endpoints

- To decrease psychosocial barriers to engagement in care by improved knowledge, decreased psychological distress, decreased stigma, and increased social support. These endpoints will be measured using the following, which will be administered via ACASI:

  - Mental Adjustment to HIV Scale (MAHIVS; Ross, Hunter, Condon, Collins & Begley, 1994): The MAHIVS is a 40-item questionnaire on a 4-point Likert scale designed to measure attitudes toward their illness and psychological adaptation for people living with HIV. Five subscales measure helplessness/hopelessness, fighting spirit/self-efficacy, denial/avoidance, fatalism, and belief in influencing the course of the disease. (See Appendix VIII)

  - Self- Efficacy for Disclosure of HIV Status (Parsons et al., 2005): There are six items where participants are asked how much they agree with statements regarding their perceived ability to disclose their HIV status to sexual partners in different situations. Participants indicate agreement using a 5-point Likert scale from 1 (absolutely sure I cannot) to 5 (absolutely sure I can). (See Appendix IX)

- HIV Stigma Scale (Berger, Ferrans, & Lashley, 2001): The HIV Stigma Scale is a 40-item instrument on a 4-point Likert scale designed to measure perceived stigma among HIV-positive populations. Reliability coefficients range from .90 to .93 across subscales providing strong evidence for internal consistency. For this study, we will include the personalized stigma and disclosure concerns subscales. (See Appendix X)

- Brief Symptom Inventory (BSI); Derogatis, 2000): Mental health issues will be assessed by the BSI, which requires only 8 to 10 minutes to complete (Derogatis & Spencer, 1982). It yields nine primary symptom scales and global indices and has norms for adolescents and adults. The reliability, validity, and utility of the BSI instrument have been tested in more than 400 research studies. Internal consistency for the sub-scales (dimensions) ranged from .71 to .85. (See Appendix XI)

- Health Belief Model – Self-Efficacy for Sexual Discussion (Lux & Petosa, 1994): The Self-Efficacy for Sexual Discussion subscale of the Health Belief Model is an 8-item scale used to assess self-efficacy to have sexual discussions among adolescents. (See Appendix XII)

- Condom Use Self-Efficacy Scale (CUSES; Brafford & Beck, 1991): The CUSES is a 28-item scale used to assess an individual's perception of his/her ability to use condoms. This scale has shown excellent internal consistency among youth (.91). (See Appendix XIII)

- HIV/STD Knowledge Questionnaire (DiClemente, 1994): The HIV/STD Knowledge Questionnaire is a 16-item true/false self-report instrument that assesses knowledge of transmission routes, misconceptions about transmission, and risk-reduction strategies. Two items also assess the participants' certainty of their HIV knowledge and personal familiarity with someone who has HIV. (See Appendix XIV)

- The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST; World Health Organization (WHO), 2002): This measure was developed for the WHO to detect psychoactive substance use and related problems in primary care patients across multiple cultures. Individuals respond to eight items assessing the frequency and consequences of drug and alcohol use. A modified version of this questionnaire will be administered in the ACASI. (See Appendix XV)

- Social Support for Adolescents Scale (SSAS; Seidman et al. 1995): This 21-item social support scale is used to assess social support among adolescents. This scale was originally developed by Cauce and colleagues (1982). Peer social support and formal social support subscales will be used for this study. See Appendix XVI)

- Nutrition and Exercise Questions: A number of items assessing the general health issues covered in the comparison intervention were added to the questionnaires. These questions were previously used in the Project ÒRÉ intervention (ATN 034; Dolcini, Harper, Boyer, Pollack & the ATN, 2010). (See Appendix XVII)

- National Youth Risk Behavior Survey (CDC, 2011): This questionnaire includes items that assess demographic information; unintentional injuries and violence; tobacco use; alcohol and other drug use; sexual behavior; body weight and dietary behaviors; physical activity; other health-related topics. A modified version of this questionnaire containing 19 items that relate to body weight and dietary behaviors, physical activity and health-related topics will be used for this study. (See Appendix XVIII)

- HIV Health Related Quality of Life Scale (HIV-HRQOL; Andrinopoulos et al. 2011): This measure includes assessment of perceived burden of symptoms of HIV measured as degree of satisfaction with domains of life that are potentially affected by HIV (e.g., social relationships, family burden, medical management), interference with life goals and daily activities, HIV-related worries and perceptions of self in relation to other adolescents. This 37-item scale has been modified for this study and administered in the ACASI. (See Appendix XX)

- Pregnancy and Parenting: Questions regarding pregnancy and parenting history and desire will be asked along with demographic questions for background, schooling, living situation, and current health. (See Appendix III)

- To decrease sexual risk as measured by fewer episodes of unprotected sex and fewer new diagnoses of STDs. These endpoints will be measured using the following:

  - Sexual Risk Behavior: This questionnaire was developed by the Behavioral Leadership Group (BLG) of the ATN and has been used in multiple studies of HIV-positive adolescents and young adults. This measure includes questions that assess condom/barrier protected and unprotected oral, vaginal, and anal sexual activity with both males and females in the past month. This questionnaire will be administered in the ACASI. (See Appendix XIX)

  - Diagnoses of STDs: Medical record abstraction will be used to collect new STDs diagnoses at each follow-up assessment. Similar information will also be collected through self-report in the ACASI. (See Appendix XXII)

3.4.2 Exploratory Study Endpoints

- To positively influence HIV biomarkers (i.e., increase CD4 levels and decrease viral load). These biomarkers will be abstracted from the participant's medical record at designated study visits.

3.4.3 Acceptability Evaluation Measures

- Participant Session Evaluation Form (SEF; Harper, Contreras, Bangi & Pedraza, 2003): The SEF is a brief 13-item paper and pencil questionnaire that will be given directly to study participants (both Project ACCEPT and HEALTH) at the end of each session. This questionnaire consists of 10 items on a 4-point response scale aimed at eliciting information about the participant's experience with the session (i.e., was the session interesting, was it relevant to their life, did they learn from the session). Three open-ended items query participants about what was most and least useful about the session. The form will be faxed (or scanned and emailed) to the Project Director. (See Appendix XXI)

- Participant Acceptability Questionnaire: Assessment of acceptability will be conducted at the end of the intervention and will be designed to assess its content and delivery. This will be done for both Project ACCEPT and HEALTH participants. We will assess: 1) the usability of the content and material; 2) user-friendliness of the presentation, delivery format, and interventionist; 3) credibility of the examples used; and 4) comprehensibility and readability of the content. We will also assess participants' perceptions of the interventionist competency and credibility. This questionnaire will be administered via ACASI. (See Appendix XXIV)

- Intervention Group Environment Scale (IGES; Wilson et al., 2008): The IGES is a 25-item measure of intervention group environments that can be used in community-based and clinical settings. Using a 4-point Likert scale, the IGES covers a broad range of potential features of intervention group environments that may impact intervention effectiveness. This questionnaire will be administered via ACASI for both Project ACCEPT and HEALTH participants. (See Appendix XXV)

4.0 SELECTION AND ENROLLMENT OF STUDY PARTICIPANTS

4.1 Inclusion Criteria

To be considered eligible for enrollment, an individual must meet the criteria listed below.

4.1.1 HIV-infected and aware of his/her status as documented by medical record review or verbal verification by provider (i.e., medical or mental health care provider, case manager, social worker, etc.);

4.1.2 Received HIV diagnosis within the past 12 months (+ 3 months) at the time of consent/assent as documented by medical record review or verbal verification with referring professional (i.e., medical or mental health care provider, case manager, social worker, etc.);

4.1.3 Between the ages of 16-24 (inclusive) at the time of informed consent/assent;

4.1.4 Receives services at one of the selected AMTUs or one of their community partners;

4.1.5 Willing to participate in both the individual and group sessions;

4.1.6 Ability to speak and understand spoken English;

4.1.7 Able to understand and willing to provide signed informed consent/assent in English or Spanish; and

4.1.8 Willingness to provide signed informed consent or assent with parental/legal guardian permission as applicable.

4.2 Exclusion Criteria

To be considered eligible for enrollment, an individual must not meet any of the criteria listed below.

4.2.1 Participated in a previous wave, if enrolling into Wave 2 or 3;

4.2.2 Intoxicated or under the influence of alcohol or other substances at the time of consent/assent;

4.2.3 Visibly distraught and/or visibly emotionally unstable (i.e., exhibiting suicidal, homicidal, or violent behavior) in the opinion of the site personnel would interfere with the ability to give true informed consent; and

4.2.4 Any concurrent participation in other behavioral studies. Permission from the protocol team may be provided for uncertain cases.

4.3 Recruitment and Screening

Potential participants will be approached for the study through the clinics by trained clinic staff, AMTU staff or other means, as applicable. They will be informed of the nature of the study, the information to be collected, and the evaluations and assessments that are involved. Individuals who express interest in the study will be required to provide signed informed consent and have eligibility criteria confirmed by the AMTU staff before enrolling into the study.

Each individual who is pre-screened (e.g., medical chart review is performed to assess potential eligibility prior to approaching the individual), approached for recruitment, screened and/or consented for study

participation will have the following information entered on a screening log that will be maintained in a secure area at the AMTU site: name, date of birth, race, ethnicity and enrollment status along with the reason(s) for not enrolling in the study, if applicable. Only those individuals that provided informed consent to participate, but were not enrolled, will have their screening log information, excluding their names, entered in the study-specific database. Individual names will remain on the screening log only. At the end of the study, the protocol team may request for composite information on those who participated in the recruitment process but did not provide informed consent and the reasons these individuals refused to participate. This data is being collected to display the general population of ATN sites that are being recruited into this study.

4.4 Informed Consent

Once it is determined that the individual may qualify for the protocol, study details will be discussed and all questions answered during the informed consent process. Signed informed consent from the individuals or assent with signed parental permission as determined by local IRB (where required) will be obtained before any study-related procedures are performed (See Appendices XXVII and XXVIII). Each site's IRB will be requested to grant a waiver of parental permission for individuals' under the age of 18 to participate in this study. The rationale for the waiver request is detailed in Section 11.5.

4.5 Contact Information

Once consented, designated site study staff will complete a Contact Information Form with the participant. Participants will be asked to provide a working phone number or valid email address through which they can be reached. Participants will also be asked to provide valid contact information for up to three family member(s) and/or friend(s) who can be called in the event the participant cannot be reached by phone or email. Participants will be asked if messages can be left at the numbers provided. Study staff will not leave messages unless expressly permitted to do so by the participant which also will be documented on this form. If permission is given to leave messages, site staff will assure participants that messages left with a family member or friend will only ask the participant to contact study staff and will not include any protected health information or information related to study participation.

The Contact Information Form will not contain any study data and will be maintained under double locks at the study site, separate from all study records, with access limited to designated site research personnel.

4.6 Co-enrollment Guidelines

Co-enrollment in other clinical studies may be considered at the discretion of the protocol team. Requests for "blanket" co-enrollment approvals into other relevant open protocols during the implementation of this protocol will be considered by the protocol team and, if meritorious, will be granted prior to implementation of this protocol.

Studies that open after this protocol is implemented can be considered for co-enrollment either by requesting a one-time, blanket approval from the protocol team OR by requesting case-by-case permission for co-enrollment in writing from the protocol chair using the ATN QNS.

5.0 STUDY PROCEDURES

5.1 Enrollment Procedures

If this is the first time an individual is participating in an ATN-sponsored study and he or she does not already have an ATN Patient Identification number (PID), site staff will assign a PID in consecutive order from the pre-printed PID-Assignment Log that is provided by the ATN DOC and record the assignment in the Log. Participants with an existing PID number will continue to use the same number. Participants who are confirmed eligible and enrolled will be assigned a protocol-specific Study Identification number (SID) from the SID list that is provided to the site by the ATN DOC after protocol registration approval is obtained. The *ATN 108 Eligibility and Enrollment Form* will be used to confirm eligibility and will be completed prior to the start of the baseline visit to enroll the participant in the study. The form must be entered into Oracle Clinical-Remote Data Capture (OC-RDC) within 24 hours of initiation of the baseline visit. Official enrollment on to this study will be the completion of the E&E form just prior to the baseline visit.

5.2 Randomization Procedures

Randomization assignments will be performed by the statisticians at the ATN DOC via the ATN website (www.atnonline.org). At the baseline visit, AMTU staff will complete an *ATN 108 Randomization Worksheet*, which contains a series of questions to verify participant eligibility. AMTU staff will log on to the ATN website and submit the worksheet information to request randomization. The site principal investigator (PI) and SC will receive an email confirming that the participant has been randomized along with the study arm assignment within two hours. Once randomization is complete, the individual sessions may be scheduled.

5.3 Intervention/Investigation Procedures

Participants will be randomized either to Project ACCEPT, or HEALTH, at the baseline visit. Both Project ACCEPT and HEALTH are matched for sessions and content over three individual and six group sessions. The combination of individual and group sessions allows for more intensive individualized attention as well as supportive group sessions. Both Project ACCEPT and HEALTH sessions will occur approximately weekly and are approximately two-hours each. The baseline visit and the first individual session may occur on the same day. Participants must complete the first individual session within 14 calendar days (+4 days) of completing the baseline visit. The individual sessions must be completed prior to onset of the first group session in order for the participant to continue on the study.

Group sessions will start once the accrual goal is met and all individual sessions have been completed. Each group session is co-facilitated by a mental health professional and an HIV-positive peer (for Project ACCEPT only). This structure was developed based on qualitative data from service providers and youth living with HIV (ATN 055), and was determined to be feasible and acceptable in ATN 068.

The group sessions should occur approximately weekly with a maximum of 14 calendar days apart from one another. Project ACCEPT and HEALTH group sessions can be scheduled on the same day as long as they are not scheduled during the same time. Interventionists will have the flexibility to schedule the group sessions around holidays, etc. Participants may miss a group session and still be allowed to continue their participation in the remaining sessions.

If it becomes apparent that a participant is becoming increasingly distressed while participating in any part of the study, the individual will be assessed by the SC (or designee) to determine whether they will be able to complete the session without experiencing undue distress. If the participant appears unable or refuses to continue participation, they will be offered a list of referral sources.

In addition, if a participant is assessed by the Interventionist, SC or staff member to be intoxicated or under the influence of alcohol or other substances during the time of the session, they will be excluded from participation, and can participate in the next session when sober. If necessary, the baseline visit and the first two individual sessions may be rescheduled as long as all are completed before the first group session.

5.3.1 Intervention Condition: Project ACCEPT

Project ACCEPT's combined individual and group sessions are aimed at addressing a range of issues that impact engagement in care for youth living with HIV, including stigma, disclosure, healthy relationships, substance use, and future life planning. Interventionists will also provide participants with referrals as needed. Examples of activities and content areas are:

SESSION	TOPICS
INDIVIDUAL SESSION 1 (PRE-GROUP)	Identification of Sources of Support; Psychosocial Assessment; Preparation for Medical Provider Meeting; Meeting with Medical Provider to ask questions and continue dialogue from the participants' initial medical appointment
INDIVIDUAL SESSION 2 (PRE-GROUP)	Review of Medical Provider Meeting; Preparation for Group Experience; Overview of Project ACCEPT; Meeting with Peer Facilitator
GROUP SESSION 1. HIV OVERVIEW	Introduction & Ground Rules; Icebreaker Activity; Tile Activity (Bonding); HIV/AIDS Education; Myths & Facts about HIV; Messages about HIV; Condom Demonstration; Overview of Condoms
GROUP SESSION 2. DISCLOSURE & STIGMA	Disclosure Scene Analysis; Steps to Disclosure; Who's on your bus? (social support); Disclosure Decision Tree; SAFE Talk; Role Play: I'm living with HIV; Dealing with Outcomes of Disclosure; Disclosure Action Plan and Medication Regimen Homework
GROUP SESSION 3. PREPARING FOR MEDICAL INTERVENTION	Overview of Clinical Procedures; Challenges to Attending Clinic; Active Participant; Problem Solving Skills Scenario; Medical Appointment Adherence Overview; Adherence Activity; Medication Adherence Overview; Medication Adherence Activity; Active Participant Action Plan
GROUP SESSION 4. HEALTHY LIVING AND SUBSTANCE USE	Healthy Living Overview; Media Influence Game; Substance Use - Grab Bag Game; Risks, Decisions and Consequences of Drug and Alcohol Use; Healthy Living Overview; Nutrition and Exercise; Stress and Individual Responses; Stress Management Techniques; Relaxation Techniques: PMR; Healthy Living Action Plan
GROUP SESSION 5F. HIV-POSITIVE SEXUALITY & REPRODUCTION FOR YOUNG WOMEN	Dimensions of Sexuality; Pregnancy Planning and Prevention; Mother To Child (MTC) Transmission; Woman Drawing; My Vagina; Safer Sex Negotiation Role Play; Sexuality Action Plan
GROUP SESSION 5M. HIV-POSITIVE SEXUALITY & REPRODUCTION FOR YOUNG MEN	Dimensions of Sexuality; Aspects of Sexual Orientation; Sexuality-related stigma; Family planning; Man Drawing; Condom Line-Up; Safer Sex Negotiation Role Play; Sexuality Action Plan
SESSION 6. GOAL SETTING & SELF-ESTEEM	Self-Esteem Team Activity; Dimensions of Self Esteem; Healthy Self-Esteem Strategies; Self-esteem & Societal stigma; Realistic Goal Setting Overview; Road Map to the Future; Group Strengths Exercise; Tile

	Activity; Closing Ceremony
INDIVIDUAL SESSION 3 (POST-GROUPS)	Discussion of Participants' Experience in the groups; Review Road Map to the Future; Facilitate Referrals; Bring in someone to increase social support (partner, family member, friend); Certificate of Completion

5.3.2 Comparison Condition: HEALTH

HEALTH is focused on general health habits, diet, nutrition, and exercise. Sessions include information on alcohol, drugs, HIV and other STDs to meet our ethical responsibility to provide risk reduction information to youth assigned to this condition. The modified HEALTH intervention parallels in number of sessions and the duration to Project ACCEPT. It has been used in similar populations, most recently in ATN 089. Interventionists will also provide participants with referrals as needed. Examples of activities and content areas are:

SESSION	TOPICS
INDIVIDUAL SESSION 1: INTRODUCTION	Introduction and Program Description; Overview of Ground Rules; Surveying the Health Risks; Weighing the Health Risks
INDIVIDUAL SESSION 2: INTRODUCTION CONT'D	Updating your I-Space Page; Personal Affirmation; Wrap-Up and Parking Lot Overview; Planning for group sessions
GROUP SESSION 1: FAMILY, PEERS AND COMMUNITY	Introduction and Icebreaker Activity; Family Roles and Responsibilities; Personal Roles and Responsibilities; Family Talk; Family Communication Tips; Peer Influences and Pressure; Friendship; Cliques and Crowds; Community Action Plan; Advocate Overview Action Plan: Advocacy; Group Presentation; Wrap-Up and Parking Lot Overview
GROUP SESSION 2: NUTRITION	Introduction; You are What You Eat and Do; Nutrition; Food Guidelines; My Meal; Foods High in…; The Dangers of Too Much Fat, Cholesterol and Sodium; How to Read Nutritional Labels; How Bad are the Fast Foods that We Love to Eat?; Wrap-Up and Parking Lot Overview
GROUP SESSION 3: CHRONIC DISEASES, EXERCISE AND LACK THEREOF	Introduction; Assessment of Our Own Exercise Patterns; Anaerobic, Aerobic, No Exercise Match Game; Nutrition and Exercise Fact vs. Myth; What is Diabetes?; What is Heart Disease?; The Day the Screens Went Black; Sit Less, Move More; Flexibility Exercises; Wrap-Up and Parking Lot Overview
GROUP SESSION 4F: SEXUAL HEALTH	Introduction; Reproductive Systems; Menstruation, Conception and Your Period; Self-Care for Females; STD Basics; HIV Basics; Fluids that Carry HIV; Behaviors that Transmit HIV; Mother-to-Child Transmission of HIV; HIV Timeline; Wrap-Up and Parking Lot Overview
GROUP SESSION 4M: SEXUAL HEALTH	Introduction; Reproductive Systems; Self-Care for Males; Testicular Exam, STD Basics; HIV Basics; Fluids that Carry HIV, MTC Transmission of HIV Overview; Behaviors that Transmit HIV; HIV Timeline; Wrap-Up and Parking Lot Overview

GROUP SESSION 5: SMOKING, ALCOHOL AND DRUG USE	Introduction; Swivel Game; Making Decisions about Drugs; Myths and Facts about Drugs; The Truth about Tobacco; Ways to Say No to Drugs; Smoking & Quitting Assessment; Rethinking Drinking; Wrap-Up and Parking Lot Overview
GROUP SESSION 6: FUTURE PLANNING AND VALUE OF EDUCATION	Introduction; I'm Not in School Anymore, Now What?; College Application Overview; What is a Resume?; You're Hired!; Intro to Employment; Values and Vocations; Vocational Exploration; Wrap-Up and Parking Lot Overview
INDIVIDUAL SESSION 3: FINAL CONTROL CONDITION SESSON	Introduction; Overview of Group Sessions; Wrap-Up & Closing Remarks

5.3.3 Using HIV-positive Peer Facilitators Only in Project ACCEPT Arm

Project ACCEPT is designed to be co-facilitated by an HIV-positive peer. This peer discusses their experiences as a youth living with HIV openly with the new participants, both in individual and group sessions. Focus group data from the ATN 068 trial of Project ACCEPT supports the importance of the peer as a core element of the intervention. Thus the peer facilitator is considered as an active element of the Project ACCEPT intervention and will not be matched across the two arms.

5.3.4 Waves

Participants will be enrolled in up to three waves, with approximately 16 participants enrolled in each wave. Project ACCEPT and HEALTH sessions will run concurrently in each wave and individual sessions may begin any time after randomization.

Each wave will last appropriately 48 weeks. Subsequent waves will not begin until all participants have completed the six-month follow-up visit and/or stopping rule conditions (See Section 10.5) are met.

5.3.5 Research Staff Training

The interventionists and peer facilitators will be trained together in order to develop rapport, cohesiveness, and a sense of community which will be beneficial during group supervision sessions. In addition, it will help to ensure common delivery across sites of the intervention content and approach. All interventionists will participate in a two-day training for Project ACCEPT and a two-day training for HEALTH. Peer facilitators will be trained in Project ACCEPT only. The trainings will include a session by session review of the intervention manuals, didactic elements (e.g., techniques, goals, etc.) as well as participatory exercises (e.g., role plays), and individualized feedback for the interventionists. This approach, which has been used in past studies, familiarizes the interventionists with the content of each session, reduces idiosyncratic delivery, and enhances fidelity.

The separate training for HEALTH, which will include the same interventionists as Project ACCEPT, will follow a similar format that includes a session by session review of the manual, sessions with mock participants, video-taping and regular review. An important component of both trainings, as well as during the implementation, will involve orientation of the interventionists and peer facilitators to fidelity assessments.

5.3.5.1 Interventionists will be trained in both arms

According to Mohr and colleagues (2009), failure to maintain equivalence in interventionist selection and therapeutic allegiance will threaten the internal validity of a study and may influence the outcomes of an RCT. In order to avoid effects associated with different interventionists, the interventionists in this study will be trained to implement both Project ACCEPT and HEALTH. Furthermore, interventionist allegiance, enthusiasm, and outcome expectations will be monitored in order to prevent interventionist bias between the two study arms and strengthen internal validity. Decay in interventionist skills and drift will be addressed through ongoing supervision and re-training, as necessary.

5.3.6 Intervention Monitoring/Quality Control

Study fidelity will be accomplished through the following methods:

- On-Site Training: Following the training, the interventionists and peer facilitators will practice delivery of both study arms with a minimum of five mock participants. These practice sessions will be digitally recorded and subsequently reviewed in weekly supervision calls with the Protocol chairs and Project Director and will help with the identification and resolution of problem areas prior to intervention implementation at the sites. (See Section 5.3.5)

- Digital recordings of sessions: All sessions (individual and group) for both Project ACCEPT and HEALTH will be digitally recorded and sent to the Project Director for review for consistency, accuracy and adherence to the manuals.

- Bi-Weekly Supervision Calls: Once the intervention sessions begin, the Project Director will provide bi-weekly supervision for interventionists and peer facilitators to discuss ongoing cases and situations.

- Facilitator logs and checklists: Interventionists and peer facilitators will complete log sheets together at the end of each session (for both Project ACCEPT and HEALTH) to document which elements of the intervention were delivered, and to record unique issues that arose. The facilitator logs will include specific components of each session and estimated time of completion. Both interventionists and peer facilitators will also rate opportunities for discussion, level of participation, and participant knowledge acquisition. Both forms will be faxed or scanned and emailed to the Project Director after each session.

- Outcome Expectancies Questionnaire for Facilitators: Outcome Expectancies Questionnaires will be completed by the interventionists and peer facilitators independently at the end of each session for both Project ACCEPT and HEALTH sessions to assess for potential biases in outcome expectancies. Five items will assess interventionists' and facilitator's expectations regarding the quality of the session, ability to achieve goals of the session and whether the session provided youth with the skills to achieve the goals of the intervention. This will allow for monitoring variability in expectancies based on study arm. These questionnaires will be faxed or scanned and emailed to the Project Director after each session.

6.0 EVALUATIONS AND MEASURES

6.1 Baseline

For the purpose of this study, participation in the baseline visit is equivalent to study enrollment.

6.1.1 Behavioral Evaluations

- Demographics (pregnancy and parenting history and desire, background, schooling, living situation, and current health);
- Engagement with Healthcare Provider;
- HTRM;
- ARV Medication Adherence;
- Health Care Utilization Survey;
- MAHIVS;
- Self-Efficacy for Disclosure of HIV Status;
- HIV Stigma Scale;
- BSI;
- Health Belief Model – Self-Efficacy for Sexual Discussion;
- CUSES;
- HIV/STD Knowledge Questionnaire;
- ASSIST;
- SSAS;
- Nutrition and Exercise Questions;
- Youth Risk Behavior Survey;
- HIV- HRQOL;
- Secondary Prevention Working Group Questionnaire; and
- STD Questions.

6.1.2 Medical and Health History

The following biomedical information will be abstracted from the participant's medical chart:

- Demographics (age/date of birth, gender, race/ethnicity);
- HIV primary medical care visits in the previous 12 weeks; and
- Lifetime ARV exposure history.

6.1.3 Clinical and Laboratory Evaluations

The following biomedical information will be abstracted from the participant's medical chart:

- STD diagnoses within the past 12 weeks;
- Most recent HIV-1 Viral load within the past 12 weeks; and
- Most recent CD4 T-cell count and percent within the past 12 weeks.

6.2 On Study Evaluations

6.2.1 Intervention Visit Evaluations

The Participant SEF will be completed by participants after each session (individual and group) for both Project ACCEPT and HEALTH.

Interventionists will also document any referrals provided to the participant after each Project ACCEPT or HEALTH session on the Participant Referral Log.

6.2.2 Follow-up Visit Evaluations

The following measures will be collected at the Post Intervention, 3, 6 and 12 Month follow-up visits for participants randomized to either Project ACCEPT or HEALTH unless otherwise stated.

6.2.2.1 Behavioral Evaluations

- Engagement with Healthcare Provider;
- HTRM;
- ARV Medication Adherence;
- Health Care Utilization Survey;
- MAHIVS;
- Self-Efficacy for Disclosure of HIV Status;
- HIV Stigma Scale;
- BSI;
- Health Belief Model – Self-Efficacy for Sexual Discussion;
- CUSES;
- HIV/STD Knowledge Questionnaire;
- ASSIST;

- SSAS;
- Nutrition and Exercise Questions;
- Youth Risk Behavior Survey;
- HIV-HRQOL;
- Secondary Prevention Working Group Questionnaire; and
- STD Questions.

6.2.2.2 Medical History

The following biomedical information will be abstracted from the participant's medical chart:

- HIV primary medical care visits in the previous 12 weeks; and
- ARV medications taken within the previous 12 weeks.

6.2.2.3 Clinical and Laboratory Evaluations

The following biomedical information will be abstracted from the participant's medical chart:

- STD diagnoses in the previous 12 weeks;
- Most recent HIV-1 Viral load within four weeks; and
- Most recent CD4 T-cell count and percent within four weeks.

6.2.2.4 Intervention Evaluations

The following measures will be completed by participants at the Post-Intervention visit for both Project ACCEPT and HEALTH:

- Participant Acceptability Questionnaire; and
- IGES.

7.0 DATA COLLECTION AND SITE MONITORING

This study follows ATN standards and recommended guidelines for data management that are specified in Chapter 8 of the ATN MOGO.

7.1 Development of Protocol and Case Report Forms

The ATN DOC, in collaboration with the Protocol Team, is responsible for the development of this protocol as well as the CRFs needed to collect the information required to implement this protocol.

7.2 Data Records

Participant-related study information will be identified through the PID and the SID on all participant CRFs and ACASI files. Participant names or other personally-identifying information will not be used on or stored with any study documents. All study-related information will be kept in double-locked, limited access areas at each study site. A log that links the names of participants to their PID and SID numbers will also be kept under double locks separate from all other research records, accessible only to the study staff, ATN site monitors, and representatives from NICHD. As described in Section 4.3, the Screening Log will also be stored in the same manner, accessible only to those personnel noted above. Original source documents for individual participants will be maintained at the respective AMTU and will be accessible only to the study staff. Data from original source documents will be transcribed on CRFs as applicable.

7.3 Data Collection

7.3.1 Case Report Forms

Study monitoring data, including information about eligibility, demographic data and monitoring untoward effects, will be collected on CRFs. All CRFs and Tools for this study will be available for download from the ATN website (www.atnonline.org). Hard copies of CRFs may be ordered from the ATN DOC via an order form on the ATN website. (See section 8.3 of the MOGO.)

All CRFs must have corresponding source documentation on file at the clinical site to substantiate all submitted data (Division of AIDS (DAIDS) Source Documentation Guidelines, see Appendix 4 of the ATN MOGO). Data edits through range checks and field inconsistencies will be built into the OC-RDC database to enable real time correction of key entries and CRF completion errors.

Data will be recorded directly on the following CRF (i.e., has no prior written or electronic record of data) and therefore, will serve as a source document for the study:

- CRF #104 – Participant Referral Log

This CRF must be signed and dated by the research site staff member recording the data.

Data will be recorded directly on the following tools (i.e., have no prior written or electronic record of data) and therefore, will serve as source documents for the study:

- Tool #3 Participant SEF
- Tools #4A through 4I Project ACCEPT Facilitator logs and checklists
- Tools #5A through 5I HEALTH Facilitator Logs and Checklists
- Tool #6 Outcome Expectancies Questionnaire for Facilitators

These Tools must be signed and dated by the research site staff member recording the data.

7.3.2 Audio Data

7.3.2.1 Media Security and Disposition

Following completion of each session (individual and group) for Project ACCEPT and HEALTH all media (audio-files) will be marked with the session title and each participant's SID or group session

number and will be logged on the Audio-file Tracking and Destruction Form. No identifying information will appear on the label of the audio-file. When not in use, all audio-files and digital recorders will be securely maintained in a locked area with limited access. The site will send copies of the audio-file via a traceable temporary secure server to the Project Director within a week after the session is completed for review. The original audio-file will be stored at the AMTU until confirmation is received that the audio-file has arrived at its destination and the review of the file has been completed. AMTU staff will proceed to destroy the original audio-file within the next one week.

The Project Director or designee will be responsible for ensuring that all received audio-files are appropriately destroyed according to the ATN Guidelines for the Destruction of Sensitive Study-Related Records and Media (see Appendix 1A-9 of the ATN MOGO) at the end of the study. The study staff at the clinical site will be responsible for appropriate destruction of the original audio-files. Destruction of all audio-files must be witnessed and documented on the Audio-file Tracking and Destruction Log that will be maintained at each of the locations.

7.3.2.2 Digital Recording Security and Disposition

Westat utilizes a temporary secure server to assist sites with transferring large electronic files (i.e., digital audio recordings) that must be transferred via a secure traceable service. The temporary secure server is a shared Westat space that is available for use to the ATN. Files are stored on this server for one week (seven calendar days); after which, the files are automatically deleted from the server.

The secure server is not recognized as a data storage system. The purpose of a temporary secure server is solely to transfer files from one institution to another.

The below procedures will be followed when using the digital secure server:

- Site staff will upload each digital recording to the temporary secure server at Westat within one week after the session and will notify the Project Director via email that the files are available for downloading within the next seven days before they are automatically deleted from the temporary secure server at Westat.

- The Project Director is responsible for downloading the files, reviewing the files for quality, and communicating directly with the site staff to ensure all the necessary data has been received and reviewed.

- Upon confirmation by the Project Director, site staff will be responsible for ensuring that all digital recordings are appropriately destroyed. Destruction will occur at each of the clinical site locations and at the Project Director's institution, and will be documented on the Audio-file Tracking and Destruction Log per procedures in the ATN Guidelines for the Destruction of Sensitive Study-Related Records and Media (See Appendix 1A.9 of the ATN MOGO).

- Any loss of data must be immediately reported to the protocol team via the ATN QNS.

7.3.3 Audio Computer-Assisted Self-Interview

All data collected using an ACASI will be installed on a portable laptop computer. The ACASI responses will remain confidential; no personal identifying information will be collected during the computer session. The participant's unique SID number will be used in order to link the interview responses to the participant's CRF data. Detailed instructions on the operation of the ACASI will be provided in the ATN 108 ACASI Operating Guide, which will be developed by the ATN DOC and provided to each participating site.

7.3.3.1 ACASI Data Security

Data collected via the ACASI are saved in an encrypted format using PGP® Whole-Disk Encryption. After a participant completes his or her survey, ACASI data will be saved in a password-protected compressed file using a Federal Information Processing Standards Publication (FIPS) PUB 140-2 and National Institute of Standards and Technology (NIST)-certified encryption and decryption engine developed by PGP®, a leader in the Security Marketplace. The file will be transferred to the ATN DOC via laptop modem within a specified number of days of data collection. Only authorized users with a login name and password will be able to gain access to the software in order to administer it to a participant; but they will not have the ability to access the saved data. After a participant completes each section of the interview, no one is able to look back at previous screens to view the information. For example, if Participant X completes Section A and goes to the restroom, the system will not allow AMTU staff to move throughout previous screens to view the participant's data. The participant can, however, simply stop and take a break if necessary. Upon transfer of the encrypted data to the ATN DOC, the data will be stored on the DOC's secured network (with firewall protection), which cannot be accessed by anyone outside of the DOC.

7.4 Data Submission

7.4.1 Case Report Forms

Study sites must follow ATN guidelines for CRF completion and entry that are specified in Chapter 8 of the ATN MOGO. Once the study database is developed, the RDC screens are available for data entry and protocol training has been completed, research staff at the sites will be responsible for ensuring that CRF data is entered into RDC within the timeframe specified on the CRF.

Each clinical site is responsible for entering data on CRFs into the OC-RDC database. Sites will complete an *ATN 108 Eligibility and Enrollment Form* and enter it into RDC within 24 hours after participant enrollment in the study. The *ATN 108 Untoward Events Form* will be completed and entered in RDC within three working days after the date of site awareness of the reported untoward event. All other CRFs must be completed and entered into the database within 14 calendar days from the date of the study visit, unless otherwise specified.

All CRFs must have corresponding source documentation on file at the clinical site to substantiate all submitted data (DAIDS) Source Documentation Guidelines, see Appendix 4 of the ATN MOGO). Data edits through range checks and field inconsistencies will be built into the RDC database to enable real time correction of key entries and CRF completion errors.

7.4.2 Tool Transmission

The following tools will be faxed or scanned and emailed to the Project Director within one week of completion:

- Facilitator logs and checklists;
- Participant SEF; and
- Outcome Expectancies Questionnaire for Facilitators.

7.4.2 Audiotape Data Transmission

The Project Director or designee will be responsible for ensuring that all received audio-files are appropriately destroyed according to the ATN Guidelines for the Destruction of Sensitive Study-Related Records and Media (see Appendix 1A-9 of the ATN MOGO) at the end of the study. Destruction of all media must be witnessed and documented on the Destruction Log, which will be sent via a traceable mail service (e.g., Federal Express) to the ATN DOC for archiving.

7.4.3 ACASI Data Transmission

The ACASI data will be saved on the laptop hard drive, encrypted and transmitted to the ATN DOC as described in Section 7.3.3.1 in an encrypted file using PGP® full-disk encryption after a study participant completes his/her interview. The file will be transferred to the ATN DOC via a phone modem within a specified number of days of data collection. It is recommended that completed interviews be transmitted at the end of each day to avoid accidental loss or damage. Detailed instructions are provided in the ATN 108 ACASI Operating Guide, which is available at each site.

7.5 Data Quality Assurance

Investigators receiving federal funding must adhere to the Code of Federal Regulations (CFR) to protect research participants and produce reliable study information. Sites participating in research sponsored by the NICHD need to have an internal quality assurance (QA) plan that will identify problems and correct errors in research study records. Sites are responsible for following the ATN data QA procedures (see Chapter 9 of the ATN MOGO).

7.6 Role of Data Management

The ATN DOC will provide instructions concerning the recording of study data on the CRFs, and entry of the data into RDC and ACASI administration and transmission. It is the responsibility of the ATN DOC to ensure the quality of computerized data for each ATN study. This role extends from protocol development to generation of the final study databases.

7.7 Study Site Monitoring and Record Availability

Site monitors from the ATN DOC will visit participating study sites to review a selected portion of the individual participant records, including assent/consent forms, CRFs and supporting source documentation to ensure the protection of study participants, compliance with the protocol, and accuracy and completeness of records. Regulatory files, as required, will also be inspected to ensure that regulatory requirements are being followed.

The site investigator will make study documents (e.g., consent forms, CRFs) and pertinent hospital or clinic records readily available for inspection by the local IRB, the site monitors, the NICHD, the Office of Human Research Protection (OHRP), or the sponsor's designee for confirmation of the study data.

8.0 PARTICIPANT MANAGEMENT

8.1 Tracking Participants / Follow-up

Youth will be contacted via the participant's preferred method of contact by the SC (or designee) and reminded of sessions and follow-up visit dates and times. Multiple contact methods will be used for youth who are difficult to reach (e.g., mail, alternate phone numbers, e-mail, text messaging - see Section 4.5).

8.2 Study Visit Management

8.2.1 Visit Windows

All sessions and follow-up visits will be completed at the AMTU. Both Project ACCEPT and HEALTH (individual and group) sessions are expected to take two hours. The baseline and follow-up visits at Post-Intervention, 3, 6, and 12 months are expected to take approximately two hours.

Individual Session 1 should be administered within 14 calendar days of the baseline visit. The visit has a window of up to 4 additional calendar days past the initial 14 calendar days after the baseline visit.

The post intervention visit should be administered within 14 calendar days following the completion of the final session (third individual session) of Project ACCEPT and HEALTH.

The follow-up visits will take place based on the schedule below:

3 Month Follow-up: approximately 12 weeks after the final session.
6 Month Follow-up: approximately 24 weeks after the final session.
12 Month Follow-up: approximately 48 weeks after the final session.

Each visit has a window of up to 14 calendar days prior to and up to 14 calendar days after the target visit date (+/- 14 days). AMTU staff must contact the protocol team for permission to conduct a visit outside the visit window.

8.2.2 Group Sessions

Group Sessions will continue as scheduled as long as two or more participants are present. If less than two participants are present, then the session will be cancelled and rescheduled for a later date.

8.2.3 Completing the ACASI

- The participant is reminded of his or her right to discontinue at any time with no penalty and the right to choose to leave any questions unanswered;
- The participant is given headphones and a laptop or desktop computer in an accommodating, private and quiet area;
- The AMTU staff assists with ACASI tutorials, if required;
- The evaluations and interventions are conducted with ACASI;
- If the participant requires a break, AMTU staff will remind the participant that they must restart within 30 minutes in order to continue where they left off. AMTU staff will make sure the computer program is exited and re-entered properly so that the participant's confidentiality is maintained; and
- If the ACASI is discontinued for any reason, the participant cannot return to complete it.

8.2.4 Debriefing and Referral Procedures for ACASI

- The participant will be debriefed about possible reactions to answering questions of a sensitive nature, such as short-term feelings of sadness or anxiety. Participants will be instructed to contact study personnel or to consult the list of referrals provided if feelings persist or worsen after several days;

- Referrals for mental health services will be provided to all participants, if warranted; and

- Before completing the ACASI debriefing, the AMTU staff member present during the session will ask the following question: "*Is there anything else about the interview that you would like to discuss?"*

  If the respondent says *"no,"* she or he should be thanked for participation. The respondent will be given contact information for mental health personnel available at the AMTU and informed that she or he can also contact study personnel in the event that issues or concerns arise later.

  If the response indicates the participant is in urgent need of mental health assistance, site staff should follow their individual site procedures for acute mental health referrals. Site staff should contact a supervisor immediately and stay with the study participant until the supervisor, mental health professional or emergency services, if needed, arrives. Otherwise, the interviewer should say, *"If you decide that you would like to speak with a counselor, here is the contact information for a counselor and a list of agencies in the community that provide this service"* and provide the list of referrals.

8.3 Compensation

The decisions around compensation will be determined separately by each site and approved by each site's IRB.

8.4 Intervening on "Social Harms"

All sites have specific policies governing the treatment of human subjects. These policies specify that medical and psychological assistance will be available in the immediate environment in the event a participant should experience any adverse reactions resulting from study procedures.

While participants will be informed that they may refuse to answer any question at any time, responses or reactions to certain questions may indicate distress on the part of the participants. If at any time during the study, a participant divulges that he or she is at risk for harm, including but not limited to being abused or experiencing violence, if harm is suspected or likely, or if the participant states he or she is suicidal/homicidal, measures will be taken to ensure his or her safety. Reporting will be done as appropriate to the situation and the legal statutes, including reporting to child protection agencies or other appropriate agencies and referrals will be provided to appropriate support, counseling or treatment resources.

8.5 Criteria for Premature Discontinuation

8.5.1 Premature Discontinuation from Study Arm

Participation in the study arm will stop permanently and the participant will remain on study and have follow-up study visit evaluations performed per the Schedule of Evaluations (Appendix I) if any of the following occurs:

- Participant causes harm to other participants (e.g., attendance of study appointments while incapacitated on substances, breaking confidentiality, overly disruptive behavior during group sessions); and

- The investigator determined that receipt of additional study intervention is no longer in the participant's best interest.

Complete the *ATN 108 Premature Discontinuation From Study Arm Form* when the decision is made to permanently discontinue the participation from the study intervention.

8 5.2 Premature Study Discontinuation

Participants will be prematurely discontinued from the study if any of the following occurs:

- Participant fails to complete both individual sessions regardless of study arm prior to the start of the group session;

- Participant fails to comply with the study requirements so as to cause harm to himself/herself or seriously interfere with the validity of the study results;

- Investigator determines that further participation would be detrimental to the health or well-being of the subject;

- Participant develops a health problem and needs treatment that would affect the results of this study;

- Development of an untoward event that warrants discontinuation from study;

- Participant moves out of area;

- Participant is lost to follow-up;

- Inadvertent enrollment;

- Participant withdraws consent/assent or parent/legal guardian withdraws permission;

- Participant becomes incarcerated or detained;

- Study is stopped by a government agency such as the NIH; and

- Study is stopped for other administrative reasons.

Complete the *ATN 108 Off Study Form* when the decision is made to permanently discontinue the participant from the study and no further study follow-up or data collection will occur. If the participant was also completing sessions in either of the study arms at the time of Premature Study Discontinuation, complete the *ATN 108 Premature Discontinuation From Study Intervention Form* as well.

9.0 MONITORING UNTOWARD EVENTS ASSOCIATED WITH OR RESULTING FROM STUDY

Site staff must first follow their own IRB's procedure for reporting and managing untoward events. ATN Behavioral and Community Prevention protocols follow the ATN Policy for Guidance for Safety and Impact Reporting (See Appendix 1-B9 of the ATN MOGO).

There are three types of untoward events to be identified: (1) those related to the participant, (2) those related to the study staff, and (3) those related to the neighborhood/community.

First, the study will catalogue any untoward event experienced by the participant. Reporting is required for occurrences including social harms, psychological distress and serious life threatening events such as suicide attempts. These may be immediately apparent to the study staff, such as the participant's emotional upset requiring referral for counseling; or they may be delayed and reported later to study staff, such as physical harm to an individual for having participated in the study. Study staff will notify the protocol team of these untoward events as soon as possible, but no later than 48 hours after awareness of the event using the ATN QNS accessible through the ATN website (www.atnonline.org). Study staff will be briefed during the training on the scope of possible untoward events and instructed to report them. Site staff will also report the untoward event on the *ATN 108 Untoward Event Form* for entry into the study database within three working days after awareness of the event.

Second, study staff may encounter untoward events during sessions that personally affect them. Training and guidance will seek to minimize this risk. Nonetheless, an assessment of the cost of conducting this study must include cataloguing these events as well. The protocol team should be notified of these events within 48 hours of occurrence using the ATN QNS so that they may be immediately addressed, evaluated, and guidance modified or expanded to minimize similar risk to other staff. Site staff will also report the untoward event on the *ATN 108 Untoward Event Form* in the same manner explained above.

Third, a critically important area any community-based study intends to evaluate is the impact, including untoward effects, of the project on the community. This will be done informally for ATN 108 with untoward events on the community being reported to the protocol team via the ATN QNS, documented on the *ATN 108 Untoward Event Form* and entered into the study database as described above.

10.0 STATISTICAL/ANALYTIC CONSIDERATIONS

10.1 Study Design

The proposed study is a two-group randomized repeated measures design (baseline and 5 follow-up points over 12 months) examining the efficacy of Project ACCEPT to improve engagement in care among youth newly diagnosed with HIV at five AMTU sites across the U.S. The primary outcome is engagement in care with secondary outcomes of decreased psychosocial barriers to care and decreased sexual risk behavior. An adaptive trial design is proposed for this study, enrolling youth in up to three waves, in order to improve the efficiency of the study by potentially decreasing the duration of the trial and enrolling fewer participants (Fitts, 2010). The adaptive criteria will be assessed by cross-sectional interim analyses conducted at the end of Wave 1 and after month three of Wave 2. The efficacy of the intervention will be assessed in both cross-sectional and longitudinal outcome analyses.

10.2 Sample Size and Power Estimates

A power analysis was performed assuming a 2% attrition rate at each time point based on the average observed attrition during the ATN 068 feasibility study. Attrition based on 2% loss at each time point results in cumulative attrition of 9%. Conservatively estimating 10% cumulative attrition would result in an estimated outcome analysis sample of 162 participants across all 3 waves. Assuming equal attrition across each study condition, an estimated 81 participants in each study condition will be enrolled; 54 male and 27 female. At a power of .80 for a two-tailed .05 alpha test, and assuming a moderate correlation of repeated measures (ρ=.3), this sample size is more than adequate to detect a medium treatment effect of .5 standard deviation units at each of the 5 follow-up time points, as well as a medium linear trend effect of up to .5 standard deviation unit between baseline and 12-month follow-up (Hedeker, Gibbons, & Waternaux, 1999). In other words, this is sufficient power to identify a statistically significant medium effect size as measured by a Cohen's *d* of .5 on the Engagement with Healthcare Provider scale at each follow-up assessment (a 4 or more point difference between groups, based on a published population mean of 19 and standard deviation of 8 on a scale from 13-52) (Bakken et al., 2000). The analysis is adequately powered to detect an additional linear trend across all time points of four point differences between groups. Because study enrollment is stratified by participant gender, we further determined that an analysis sample of 162 (assuming equal attrition by gender resulting in 108 male and 54 female) is adequate to identify medium size treatment by gender effects in repeated measures ANOVA or multiple linear regression (f^2= .21, equivalent to a Cohen's d=.5) (Faul et al., 2007).

Given the adaptive clinical trial design of the study, we assessed the power of the estimated sample size should the study be stopped prior to Wave 3. Using the same attrition assumptions, we estimate that outcome data might be limited to a sample size of 110 (Wave 1 and Wave 2). In either scenario, the repeated measures analysis is likely to be underpowered. However, the sample would detect medium effect size differences (d=.53) between treatment groups at the end of the study (12-month follow-up), and large gender effects (d=.63). For example, the sample is adequate to detect a statistically significant treatment effect given a difference of at least 4.2 points (Wave 1+2) on the Engagement with Healthcare Provider scale or a gender effect given a difference of at least 5 points.

10.3 Selection of Participants for Analysis

Although usually associated with effectiveness trials, we plan to implement an intent-to-treat (ITT) approach to the study analysis. ITT is a hallmark of RCT and requires that all study randomized subjects be included in outcome analyses in the study condition in which they were assigned regardless of actual treatment or adherence to the research protocol. After being assigned to a study condition, subjects may not actually use the treatment or intervention, may use less than intended doses, or may drop out from the research program and therefore have indeterminate outcomes. These subjects may differ systematically from those who follow the protocol, and their removal can invalidate random assignment, introduce bias, and lead to inappropriate interpretation of statistical tests. We also will include measures of intervention exposure, or dosage, to some analyses as a method of assessing the effect of study drop-out.

10.4 Study End Points and Outcome Measures

Most study endpoints are validated scales which will be analyzed as continuous outcomes. Some scales may be collapsed into categorical or dichotomous outcomes (e.g., high versus low, or tertiles) for analysis. Other behavioral or clinical endpoints will result in dichotomous, categorical or count outcomes (e.g., presence or absence of STD, number of STDs, number of risky behaviors). HIV biomarkers will be assessed as continuous outcomes and collapsed into categories such as CD4<200, 200-350, 351-500 and >500, as well as viral load detectable versus undetectable. (See Section 3.4)

10.4.2 Primary Study Endpoints

- Engagement in care as measured by HIV medical appointments and engagement with medical providers will be collected in the following formats:
  - Medical record review of appointment adherence to HIV primary care visits in the previous 12 weeks;
  - Engagement with Healthcare Provider Questionnaire;
  - HTRM;
  - ARV Medication Adherence; and
  - Health Care Utilization Survey.

10.4.2 Secondary Study Endpoints

- Psychosocial barriers to engagement in care examining improved knowledge, decreased psychological distress, decreased stigma, and increased social support will be measured using the following:
  - MAHIV;
  - Self-Efficacy for Disclosure of HIV Status;
  - HIV Stigma Scale;
  - BSI;
  - Health Belief Model – Self-Efficacy for Sexual Discussion;
  - CUSES;
  - HIV/STD Knowledge Questionnaire;
  - ASSIST;
  - SSAS;
  - Nutrition and Exercise Questions;
  - Youth Risk Behavior Survey; and
  - HIV-HRQOL.
- Sexual risk will be measured by fewer episodes of unprotected sex and fewer new diagnoses of STDs using the following measures:
  - Secondary Prevention Working Group Questionnaire; and
  - Diagnoses of STDs.

10.4.3 Exploratory Study Endpoints

- CD4 T + cell count and percent; and
- HIV-1 RNA viral load.

10.4.4 Acceptability Evaluation Measures

- SEF;
- Participant Acceptability Questionnaire; and
- IGES.

10.5 Statistical Analysis Plan

10.5.1 Interim Analysis Plan

The adaptive clinical study design necessitates interim analysis of outcome data prior to initiating Wave 3. The goal of the interim analysis is to curtail the study if a null or negative effect is accruing to the experimental treatment group (Project ACCEPT). Such interim analysis are part of a family of stopping rule tests known as group sequential test designs, and complex designs can be found in large clinical trials with multiple decision arms (Kittelson & Emerson, 1999). In smaller trials such as the proposed study with only one adaptation decision, it is possible to use a fixed-sample one-sided t-test analogy such as Cohen's d for the stopping rule test (Pocock, 1977). In order to provide adequate time for the remaining interim analysis (prior to wave 3) wave 3 will be delayed by one month.

Given the potential benefit of Project ACCEPT, and the cost and effort involved in initiating the study, Type II error is a particular concern of interim analysis. The interim analysis will not have sufficient power prior to Wave 2 to allow us to confidently conclude that a finding of no difference between conditions is not due to chance across the multiple tests. Therefore, stopping rules will be based on interim analysis conducted using all 12 months of Wave 1 follow-up and the first 3 months of Wave 2 (n~=110).

As soon as the 12-month follow-up data for the Wave 1 participants and the corresponding 3-month follow-up data for Wave 2 participants are available for analysis (approximately 4 weeks later, or Year 2 Month 8), we will examine differences between the study groups on the three primary outcome measures (Medical record review of appointment adherence to HIV primary care visits in the previous 3 months; Engagement with Healthcare Provider Questionnaire; and Health Care Utilization Survey) representing the primary outcome domain of engagement in care. Differences between the two study conditions on each of the three outcome measures will be converted into a standardized effect size (Cohen's d), and averaged. The sample size will be adequate to detect a medium to large effect size difference (>=.6). Therefore, a finding of a significant ($p<.05$) and large (d>=.8) effect size in favor of the HEALTH condition will trigger a Protocol Team review prior to implementing Wave 3. All primary, secondary and exploratory outcome measures will be reviewed as well as any untoward events and study dropout, and the team will decide on the benefit of continuing to Wave 3 given evidence of a null or negative effect of Project ACCEPT.

Continuation review trigger: An interim analysis finding of a large average effect size (Cohen's d >=.8) in favor of HEALTH over Project ACCEPT in the primary outcome domain of Engagement in Care, then review all evidence prior to implementing Wave 3.

Year	Wave	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
1	I			B/L	Intervention	Post-Test				3 mo-F/U			6 mo-F/U
	II												B/L
	III												
2	I						12 mo-F/U						
	II	Intervention	Post-Test				3 mo-F/U			6 mo-F/U			
	III									B/L	Intervention	Post-Test	
3	I												
	II			12 mo-F/U									
	III			3 mo-F/U			6 mo-F/U						12 mo-F/U

10.5.2 Outcome Analysis Plan

All study measures will be examined descriptively and checked for missing data, outliers, and normality of distribution. Non-normally distributed interval level variables will be transformed using standard procedures such as logarithm or categorization. In preliminary outcome analysis, we will examine the association between study condition and study outcomes first by graphing the observed relationships over time. Second, these relationships will be examined using bivariate correlations and tests of association among the independent variable (study condition), dependent variables (outcome measures), and relevant covariates, such as individual demographic and clinical characteristics, Project ACCEPT/HEALTH fidelity and attendance, study site and study wave. Covariates that are highly correlated with outcome measures will be retained in multivariable analysis, as will covariates that differ significantly between study conditions. Highly correlated covariates will be examined separately to avoid multicollinearity in regression models.

The goal of the Aim 1 outcome analysis is to test the null hypotheses of no difference between study conditions in 3 domains: 1) engagement in care (Hypothesis 1a); 2) psychosocial barriers to care (Hypothesis 1b); and 3) sexual risk behavior (Hypothesis 1c).

To address each hypothesis, multivariable longitudinal statistical analysis will be conducted using random regression modeling (RRM), a form of multilevel analysis that specifically accommodates statistical issues commonly found in longitudinal data including: serial correlation; state dependence; individual heterogeneity; missing observations; and time-fixed and time-varying covariates. The multiple levels of measurement in these models are the individual (level 2), and the repeated measurement occasions (level 1). RRM models will be run using SuperMix, a specialized software for mixed effects models developed under an NIH-grant- SuperMix, 2010 (http://www.ssicentral.com/supermix/index.html). Because of the relatively small number of sites and waves (three each), these will be treated as fixed rather than random effects in the models.

For each outcome measure in a domain, the effect of Project ACCEPT compared to HEALTH will be tested using multivariable linear or logistic RRM, for continuous or nominal/ordinal outcomes, respectively. For example, the domain of engagement in care (H1a) incorporates three outcome measures (appointment adherence, visit constancy, and the Engagement with Healthcare Provider scale), and an RRM will be fit to the data for each. In addition to study condition, each RRM model will include a random intercept, measures of linear and (if indicated in graphical analysis) nonlinear time, and fixed effects of study condition, site, wave, and relevant covariates as identified in the literature and confirmed in the bivariate analysis. Statistically significant ($p<.05$) study condition effects in the direction of the stated hypotheses will be considered support for rejecting the null hypothesis. Additional analysis will test for gender differences in the effect of Project ACCEPT (study condition by gender interaction).

A second analysis goal is to explore the relationship between HIV biomarkers and participants' level of engagement in care (Exploratory Aim). The statistical approach taken will be similar to that used in Aim 1. First, the observed relationship between measures of engagement in care and biomarkers (CD4 and viral load) will be examined graphically over time and tested using bivariate measures of association. Then CD4 and viral load will be modeled separately using measures of engagement with care as independent variables, and other covariates as described above in RRM. If there is excessive missing biomarker data, or inadequate variance in the biomarker data, a simpler approach may be taken, such as cross-sectional logistic regression models predicting ever having a CD4<350 or a detectable viral load. Statistically significant associations between engagement and biomarkers will be considered as empirical support for the exploratory aim, and further analyses of gender or other variations in the relationship will be conducted.

10.6 Missing, Unused and Spurious Data

Every effort will be made to ensure that the amount of missing data is kept to a minimum as missing data complicates the statistical analysis or results in biased parameter estimates.

Several procedures will be used to conduct data analysis when data for either outcomes or covariates are missing. The first step will be to assess the extent and pattern of missing data. If data are missing for only a few cases, then data analysis will be conducted only on study participants with complete data. However, when such a strategy would result in loss of data from a substantial proportion of participants, or if this approach would lead to biased or inaccurate results, then some form of imputation will be performed. The form of imputation used will depend on the nature of the data that are missing. For example, data that are collected repeatedly might be imputed using the "last value carried forward" method; and in some instances, interpolation between neighboring points might also be used.

When the primary endpoint is missing, one data analysis will be conducted using only cases with the endpoint. Subsequent analysis will be done where missing endpoints are imputed. Hot-deck imputation or regression imputation may also be used in this context.

11.0 HUMAN SUBJECTS

This study will be conducted in compliance with the protocol, International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines, and 45 CFR Part 46.

11.1 Participants' Confidentiality

All questionnaires, including the ACASI, evaluation forms, reports, and other research-related records will be identified by a coded number only, to maintain participant confidentiality. All records with personally-identifying information will be kept in a locked, limited access area (such as a locked file cabinet). All computer entry and networking programs will be done with coded numbers only. Clinical information will not be released without written permission of the participant (and parent or legal guardian, when applicable), except as necessary for monitoring by the ATN DOC or NICHD.

11.2 Certificate of Confidentiality

To further protect the privacy of the study participants, the ATN has obtained a Certificate of Confidentiality from DHHS. With this Certificate in place, the ATN researchers cannot be forced to turn over identifying information about a study participant in any Federal, State, or local criminal, administrative, legislative, or other proceedings. This Certificate does not prevent a study participant from

volunteering to turn over their research information nor does it prevent researchers from providing research-related information to others when requested by the study participant.

11.3 Risks and Benefits

11.3.1 Risks

Risks to participants in this research study may include:
Protocol Team's opinion of Risk Category: Research not involving greater than minimal risk (45 CFR §46.404 and 21 CFR §50.51)

Participation in this study poses no more harms or discomforts to research participants than they may experience in normal daily life or during routine physical or psychological examinations or tests.

Participation in this study does not involve any physical risk. However, there is some risk of breach of confidentiality in a group setting, emotional discomfort talking about things in the sessions and/or when responding to ACASI questions. Participants will be informed that they are free to decline to answer any questions, or withdraw from participation at any time without penalty. Participants will be told, both in the informed consent/assent and directly by the interventionist at the beginning of the sessions that they will need to respect the privacy of other members in the group. Participants will be instructed to contact study personnel or to consult the list of referrals provided if feelings persist or worsen after several days. If the response indicates the participant is in urgent need of mental health assistance, site staff should follow their individual site procedures for acute mental health referrals. Site staff should contact a supervisor immediately and stay with the study participant until the supervisor, mental health professional or emergency services, if needed, arrives.

11.3.2 Benefits

While there is no guarantee of direct benefit to the youth that participate in this study, benefiting from participating is not unlikely. Participants may benefit from the support and new information learned through the intervention sessions. The session may help the participant better understand his health needs and risks. The skill building and risk reduction intervention components of the intervention sessions have the potential to improve mental health functioning and reduce risk factors for problem behaviors, resulting in improved quality of life.

11.4 Institutional Review Board Review and Informed Consent

This protocol, the informed consent documents and any subsequent modifications will be reviewed and approved by the IRB or ethics committee (EC) responsible for the oversight of the study. The informed consent will describe the purpose of the study, the procedures to be followed, and the risks and benefits of participation.

Signed informed consent will be obtained from the participant (or parent, legal guardian, or person with power of attorney for participants who cannot consent for themselves). The participant's assent must also be obtained if he or she is able to understand the nature, significance, and risks of the study. The signed original consent/assent form will be kept on file at the site and a copy of the consent/assent form will be given to the participant and to the parent or legal guardian, if applicable. Sample informed consent/assent forms are included in Appendices XXVII and XXVIII.

Protocol Team's opinion of Risk Category: Minimal Risk

Permission will be sought from at least one parent or guardian in accordance with local IRB/EC approved procedures unless the IRB/EC has waived the requirements for obtaining parental or guardian permission in accordance with 45 CFR §46.408(c).

Assent of the children involved in this study will be sought in accordance with the regulations at 45 CFR §46.408(a) or 21 CFR §50.55 and local IRB/EC-approved policies and procedures.

11.5 Waiver of the Requirement for Parental Permission for Special Circumstances

The site IRBs will be requested to grant waiver of parental permission to participate in this research study for youth participants under the age of 18.

Under 45 CFR 46.408 (c), an IRB has the authority to waive parental permission if it determines that "a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects" and "an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted" and "that the waiver is not inconsistent with Federal, state, or local law."

The protocol team would submit that:

- This study is not considered greater than minimal risk. Participants will complete surveys and participate in individual and group sessions with other HIV-positive youth. None of the content of this study is beyond what would be covered during routine medical or psychological visits or procedures related to the problem behaviors being studied. The probability of harm from participating in this study is no greater than that occurring in routine care;

- The ATN sites involved in the study and most other community agencies offering HIV-related services are confidential and do not require parental/legal guardian notification or permission to treat under state regulations;

- Contacting a parent/legal guardian could constitute a breach of confidentiality for these HIV-positive participants and could potentially put some HIV-positive youth at risk for abuse or ousting from the home if parents/guardians are not aware of their HIV status;

- It is expected that there will be participants who have not disclosed their HIV status to parents/guardians nor will the parents/guardian be aware of the participant's risk behaviors. A requirement for parental permission in this type of study could not only affect a person's willingness to participate, but could also potentially impact the ability of researchers to engage in this type of HIV-related research with youth;

- It is expected that there will be participants who identify as lesbian, gay, bisexual, transgender and questioning (LGBTQ) youth. Commonly these youth have explored their sexual orientation without their parents' knowledge as the youth struggle with issues of disclosure and its consequences within the social, religious, and economic context of their families. If the purpose of requiring parental permission as stated in CFR is to protect the minor subject, then requiring parental permission for youth in these circumstances is not a reasonable requirement; and

- Adequate protection has been substituted by the mechanisms in place to protect the privacy and confidentiality of participants and by the treatment referrals offered if needed.

11.6 Requirement for Consenting Subjects Enrolled as Minors Who Reach Age of Majority While on Study

11.6.1 Studies Requiring Parental Permission for Minor Enrollment

When a minor participant is enrolled with parental permission into an ATN study that will extend beyond the participant's age of legal majority, ATN research staff must establish a mechanism to track the participant to obtain a legally effective consent when the subject reaches majority as long as the participant stays actively engaged in the study.

11.6.2 Studies Requesting Waiver of Parental Permission for Minor Enrollment

When an IRB/EC has waived the requirement for parental permission for minors enrolling in an ATN study, the IRB, in effect, has judged that the study meets the criteria set out in 45 CFR 46.408(c) and has waived consent for participation in the study, minor subjects in these studies need not be re-consented when they reach age of majority.

11.7 Prisoner Participation

The ATN and NICHD have concluded that this protocol does NOT meet Federal requirements governing prisoner participation in human subject research and should NOT be considered by local IRBs for the recruitment of prisoners. Subjects enrolled who subsequently become incarcerated or are placed in detention may not continue study participation. Study visits cannot be conducted during the period of incarceration or detention.

Enrolled participants who subsequently become incarcerated or are placed in detention may not continue study participation during the period of incarceration or detention. A participant may resume participation in the study after being unconditionally released from incarceration, i.e., he is not bound by home surveillance, probationary, or any type of required systematic monitoring that keeps the subject actively engaged in some form as a detainee in the social justice system, and as permitted by individual site IRBs.

A participant who continues participation after being released from incarceration must be re-assessed to ensure that he fully understands the protocol and is able and willing to adhere to protocol requirements. This assessment should be documented in the subject's source documents and in accordance with the site IRB requirements.

11.845 Information ("Privacy Rule" Pursuant to the Health Insurance Portability and Accountability Act - HIPAA)CFR Parts 160 and 164 Standards for Privacy of Individually Identifiable Health

Each site is responsible for adherence to their individual institution's HIPAA policies and procedures.

11.9 Study Discontinuation

This study may be discontinued at any time by the NICHD.

12.0 PUBLICATION OF RESEARCH FINDINGS

Publication of the results of this trial will be governed by ATN policies as outlined in Appendix 1A of the ATN MOGO. Any presentation, abstract or manuscript will be made available for review by the study sponsors prior to submission.

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APPENDIX I: SCHEDULE OF EVALUATIONS

Measure	Baseline	Individual Session 1	Individual Session 2	Group Session 1	Group Session 2	Group Session 3	Group Session 4	Group Session 5	Group Session 6	Individual Session 3	Post-Intervention	3 month follow up	6 month follow up	12 month follow up
Medical and Health History[1]	X										X	X	X	X
Clinical and Laboratory Evaluations[2]	X										X	X	X	X
ACASI[3]	X										X	X	X	X
Participant SEF[4]		X	X	X	X	X	X	X	X	X				
Referral Log[5]		X	X	X	X	X	X	X	X	X				
Participant Acceptability Questionnaire[6]											X			
Intervention Group Environment Scale[6]											X			
Facilitator Logs and Checklist[7]		X	X	X	X	X	X	X	X	X				
Outcome Expectancies Questionnaire for Facilitators[7]		X	X	X	X	X	X	X	X	X				

[1]At baseline, abstract demographic information (age/date of birth, gender, race/ethnicity, etc.), HIV primary care visits within the previous 12 weeks and ARV exposure history. At all other visits, abstract HIV primary care visits within the previous 12 weeks and ARVs taken within the previous 12 weeks.
[2]At baseline, abstract all STD diagnoses within the past 12 weeks and the most recent HIV-1 viral load and CD4 T-cell count and percent within the past 12 weeks. At all other visits, abstract STD diagnoses within the previous 12 weeks, HIV-1 viral load and CD4 T-cell count and percent within 4 weeks around the visit date.
[3]See Section 6.1 for measures given at Baseline. See Section 6.2 for measures given at all other visits.
[4]Completed by the participant.
[5]Completed by the interventionist.
[6]Completed by the participant as part of the ACASI.
[7] Completed by the interventionist and peer facilitator.

APPENDIX II: LIST OF PARTICIPATING SITES

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ATN Site 16 St. Jude Children's Research Hospital Department of Infectious Diseases 262 Danny Thomas Place, Mail Stop 600 Memphis, TN 38105	PI: Aditya Gaur, MD Email: pat.flynn@stjude.org Phone: (901) 595-2338 Fax: (901) 595-5068
ATN Site 18 Baylor College of Medicine Texas Children's Hospital 1102 Bates Street, Suite 630 Houston, Texas 77030	PI: Mary Paul, MD Email: mpaul@bcm.edu Phone: (832) 822-1038 Fax: (832) 825-1281
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APPENDIX III: DEMOGRAPHIC QUESTIONS

DemIntro I am going to ask you some questions about your background, schooling, living situation, and current health. Everything you answer is confidential.

DemAge How old are you?

_____ years

DemBirth Were you born a male or a female?

Male
Female

DemCurr What is your current gender?

Male
Female
Transgender

DemHispanic Are you of Hispanic (Spanish) or Latino origin?

Yes
No ***(Skip to DemRace)***

DemHispanicSpec Are you:

Central American
Cuban
Dominican
Mexican, Mexican-American, or Chicano
Puerto Rican
Mixed Hispanic background
South American
Other

DemRace What is your race/ethnicity?

Asian/Pacific Islander
Black/African American
Native American/Alaskan Native
White
Mixed race
Other

DemID How do you identify?

Straight

Gay / Lesbian
Bisexual
Questioning

DemFatherKnowMSM Does your father know you have sex with other men?

Yes ***(Skip to DemFatherFindOut)***
No ***(Skip to DemMotherKnowMSM)***
Suspects it, but I'm not sure that he knows ***(Skip to DemMotherKnowMSM)***
I am not in contact with my father

DemNoContactFather Are you not in contact with your father because he found out that you have sex with other men?

Yes
No

DemFatherFindOut When did your father find out you have sex with other men?

Within the past year
More than 1 year ago, but less than 2 years
More than 2 years ago
Don't know

DemFatherTell Who told your father that you have sex with other men?

I told him
Someone told him with my permission
Someone told him without my permission
Someone told him anonymously
He found out some other way

DemMotherKnowMSM Does your mother know you have sex with other men?

Yes ***(Skip to DemMotherFindOut)***
No ***(Skip to DemInSchool)***
Suspects it, but I'm not sure that she knows ***(Skip to DemInSchool)***
I am not in contact with my mother

DemNoContactMother Are you not in contact with your mother because she found out that you have sex with other men?

Yes
No

DemMotherFindOut When did your mother find out you have sex with other men?

Within the past year
More than 1 year ago, but less than 2 years
More than 2 years ago
Don't know

DemMotherTell Who told your mother that you have sex with other men?

I told her
Someone told her with my permission
Someone told her without my permission
Someone told her anonymously
She found out some other way

DemInSchool Are you in school these days? By school, I mean a school or program where you are working toward a high school diploma, GED, or college/technical degree.

Yes
Yes, but I am on summer break now
No

DemYears What is the highest grade you have completed?

Eighth grade or less
More than eighth grade but did not complete High School
High School Graduate
GED
Some College/Technical Education
Technical School Graduate
College Graduate
Graduate School/No degree
Master's Degree or above

DemTest When did you test positive for HIV?

DemAIDS Have you been given a diagnosis of AIDS?

Yes
No

DemTreat When did you first seek medical treatment for HIV?

DemTreatEdit In what year did you first seek medical treatment for HIV?

|_____|_____|_____|_____| "Year"

DemPay How do you pay for your medical treatment?

Public insurance (Medicaid, SSI)
Private insurance
Out of pocket / Cash
Other

DemPaySpec Please specify: _____

MedHIV Are you currently taking medication for HIV?

Yes
No ***(Skip to PregTimes)***

MedWhen When did you begin taking HIV medications? **MedWhen.wav**

MedWhenEdit In what year did you began taking HIV medications?

Don't know

Pregnancy & Parenting History

PregTimesMale How many times have you gotten a partner pregnant?

PregTimesFemale How many times have you been pregnant? ***(If PregTimesFemale > 0 skip to PregAgeFemale. If PregTimesFemale = 0, skip to PAISAttitude)***

PregAgeMale How old were you when you first got a partner pregnant?

_____ years

PregAgeFemale How old were you when you first got pregnant?

_____ years

PregAbort Of these pregnancies, how many resulted in abortions?

PregMisc Of these pregnancies, how many resulted in miscarriages?

PregBirth Of these pregnancies, how many resulted in births?

PregChild <if first child display "Child 1" text otherwise display "Child 2" text.>

PregHIVMale How many times have you gotten a partner pregnant since you learned you were HIV positive?

PregHIVFemale How many times have you been pregnant since you found out you were HIV positive?

PregChildHIV How many children have you had since you found out you were HIV positive?

PregChildHIVSpec Please tell us more about the children that you have had since you found out that you were HIV positive. In what year was this child born?

PregChildHIVPos Please tell us more about the children that you have had since you found out that you were HIV positive. Is this child HIV positive?

Yes
No

PregNow Are you pregnant now?

Yes
No
Do not know

PregAbort3Mos In the past 3 months, have you had an abortion?

Yes
No
Do not know

PregMisc3Mos In the past 3 months, have you had a miscarriage?

Yes
No
Do not know

APPENDIX IV: ENGAGEMENT WITH HEALTH CARE PROVIDER

Please rate on a scale of 1 (always true) to 4 (never true) how truetrue the statements below describe your interactions with your HIV health care provider. By HIV health care provider, we mean your doctor, nurse practitioner or physician assistant.

1	2	3	4
Always true	True Most of the Time	Sometimes True	Never True

1. Listens to me
2. Cares about me
3. Answers my questions
4. Spends enough time with me
5. Involves me in decisions
6. Respects my choices
7. Deals with my problems
8. Engages me in my care
9. Is helpful to me
10. Respects me
11. Supports my decisions
12. Sees me when I ask
13. Provides me with information

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APPENDIX V: ARV MEDICATION ADHERENCE QUESTIONS FOR ATN STUDIES

Now we're going to ask you some questions about your HIV medicines.

1. Are you currently taking pills or other medicines to treat your HIV?
   a. Yes ***(Go to 2)***
   b. No ***(Go to 14)***

Intro before question 2: Many people with HIV have many pills or other medicines to take at different times during the day. Often people find it hard to always remember to take their pills or medicines. Sometimes people get busy and forget to carry their pills with them. Other times people find it hard to take their pills like their doctor told them to, such as "with food" or "on an empty stomach" or "every 8 hours." Other times people decide to skip pills to avoid side effects (like feeling sick to your stomach) or to just not take pills that day.

It is important for us to understand what people with HIV are really doing with their pills or medicines. Please tell us what you are actually doing. Don't worry about telling us you don't take all your pills or medicines. We want to know what is really happening, not what you think we want to hear.

2. How many times during the day had your doctor told you to take doses of medicine (pills or other medicines) to treat your HIV?
   a. Once a day
   b. Twice a day
   c. Three times a day
   d. Four or more times a day

3. What is the total number of pills your doctor has told you to take each day? (Please type in the total number of pills below.)

4. Now we're going to ask you to think about last weekend (Friday, Saturday and Sunday). Sometimes taking medication can be even more difficult on weekends. Thinking about the last weekend, how many doses did you miss? (Please type in a number from 0 (which means you didn't miss any doses last weekend) to as many doses as you might have missed.)

5. Now we're going to ask you to think about the last 7 days. In those last 7 days, how many doses of your HIV medication did you miss in the last 7 days? (Please type in a number from 0 (which means you didn't miss any doses) to as many doses as you might have missed.)

6. Did anything happen in the last 7 days that made it more difficult to take the medicine your doctor prescribed for you?
   a. Yes
   b. No (skip to 8)

7. If you missed taking any pills over the last 7 days, what were some of the reasons? (Please answer "yes" to anything that made it hard to take each and every dose of medication.)

   Answer options for 7A through 7R are "Yes" and "No."
   a. Can't get pill at drug store
   b. Ran out of prescription
   c. Did not have health insurance to pay for the prescriptions

d. Made me sick to my stomach/tasted bad
e. Forgot
f. I got a headache or rash or other physical symptom
g. It got in the way of my daily schedule (school, work)
h. Didn't feel like taking it, needed a break
i. Change in living situation, moved
j. Worried that someone would find out about the HIV
k. Got sick with another illness, wasn't feeling well (e.g., cold, flu, etc.)
l. Don't think I need the pills anymore, I can stay healthy without it
m. Family and/or friends don't help me remember
n. Family and/or friends tell me I shouldn't take it
o. Nowhere to keep the pills at school or work
p. Don't understand why I have to take the pills
q. I keep getting sick even when I do take the pills
r. Taking it reminds me of the HIV, I just want to forget about the diagnosis
s. Other: (please type in the answer): _____

8. In the last 7 days, did you do anything to help you remember to take your pills (or medicine)?
a. Yes
b. No (skip to 10)

9. Please select all of the things you did to help you remember to take your pills.
a. Labels
b. Calendars
c. Pill boxes
d. Beepers
e. Monitoring caps (MEMS)
f. Timers
g. Programmable wrist watches
h. Diary
i. "buddy system" (someone who helps me to remember)
j. Always taking the pills when a certain thing happens during the day (for instance, every time you eat breakfast)
k. Other: (please type in response): _____

10. Is there a pill or medicine that is really hard for you to take?
a. Yes
b. No (skip to 13)

11. Which pill or medicine is hard for you to take? (Please type in the name of the pill or its color.)

12. What makes the pill or medicine hard to take? (Please type in a brief answer.)

13. Has your doctor offered or prescribed pills or other medicines for your HIV infection but you never started taking those medicines?
a. Yes
b. No

14. Have you been prescribed pills or other medicines for your HIV infection that you took for awhile but have now stopped completely?

a. Yes
b. No (skip to 16)

15. What were some of the reasons that you stopped taking pills or other medications for your HIV infection? (Please answer "yes" to anything that made it hard to take each and every dose of medication.)

Answer options for 15A through 15R are "Yes" and "No."

a. Couldn't get pill at drug store
b. Ran out of prescription and never started again
c. Did not have health insurance to pay for the prescriptions
d. Made me sick to my stomach/tasted bad
e. Forgot
f. I got a headache or rash or other physical symptom
g. It got in the way of my daily schedule (school, work)
h. Didn't feel like taking it, needed a break
i. Change in living situation, moved
j. Worried that someone would find out about the HIV
k. Got sick with another illness, wasn't feeling well (e.g., cold, flu, etc.)
l. Didn't think I needed the pills anymore, I could stay healthy without it
m. Family and/or friends didn't help me remember
n. Family and/or friends told me I shouldn't take it
o. Nowhere to keep the pills at school or work or home
p. Didn't understand why I had to take the pills
q. I kept getting sick even when I did take the pills
r. Taking it reminded me of the HIV, just wanted to forget about the diagnosis
s. Other: (please type in the answer):

Health care providers have different styles in dealing with patients. We would like to know more about how you feel about your care provider. Answer these questions by thinking of the main health care provider you see at your clinic. Please indicate how you felt during your most recent visit to your care provider. Your responses are confidential. Please be honest and truthful. Indicate how much you agree with each of the following statements.

Answer options for questions 16 through 20 are as follows:

a. Strongly disagree
b. Somewhat disagree
c. Neutral
d. Somewhat agree
e. Strongly agree

16. I feel that my care provider has provided me with choices and options.

17. I feel understood by my care provider.

18. My care provider conveys confidence in my ability to make changes.

19. My care provider encourages me to ask questions.

20. My care provider tries to understand how I see things before suggesting a new way to do things.

We are interested in learning more about where you are living.

21. Which of the following best describes your current housing situation?
    a. Apartment
    b. Single family home
    c. Group home
    d. Room in hotel
    e. Room in someone else's house/apartment
    f. Rehabilitation or health facility
    g. Street
    h. Shelter
    i. Juvenile detention center/jail/prison
    j. College/University residence hall
    k. Other (please type in where): _____

22. Thinking about the last year, how many times have you moved? (Please type in the number of times (0 means you haven't moved in the last year) up to as many times as you have lived in different places in the past year.)

    Note to programmer: maximum 50

23. What is the zip code of the place where you live now?

24. Do you anticipate having to move in the next three months?
    a. Yes
    b. No

25. How ready are you…

ISSUES	**Not Ready or Able to Change = (1) Completely Ready and Able to Change = (10)**	**Or: I Don't ….**
25a. To take medication as prescribed (if you are not on medications, answer about your willingness to take medications as prescribed, i.e., if you are not at all willing choose 1, if you are completely willing choose 10).	1 2 3 4 5 6 7 8 9 10	I Don't Seek Medical Care (0)
25b. To get to medical appointments (at least 4 times a year).	1 2 3 4 5 6 7 8 9 10	I Don't Seek Medical Care (0)

APPENDIX VI: YOUNG ADULT 1 MONTH ADHERENCE INTERVIEW

These questions are about taking medications for HIV. For each one, tell me the percent (%) from 0 to 100 that best answers the question for you. Percent is "percent of the time." 0% would mean "NONE of the time" or "NEVER," 50% would mean "half of the time", and 100% would mean "ALL of the time" or "ALWAYS." Numbers in between would mean amounts between NEVER and ALWAYS. You might want to think about it as a line with 0% at one end, with 100% at the other end, and with the other numbers in between.

1. _____% In the past month, what percent of the time did you take your medicine?

2. _____% In the past month, what percent of the time did you take all the doses for the day?

3. _____% In the past month, what percent of the time did you take your medicine according to the directions? For example at the right time, or with food, or on an empty stomach?

APPENDIX VII: HEALTHCARE AND HEALTHCARE UTILIZATION

The next section asks about your health and your use of healthcare services, including mental and physical healthcare services. Think of all the healthcare services you have received whether it was at the ATN clinic or elsewhere.

Health Care Utilization and Provider Questions

Now I would like to ask you if you have ever seen a psychiatrist, psychologist, marriage & family therapist, or social worker about the way you were feeling or behaving?
Yes
No

Now I would like to ask you if you have seen a psychiatrist, psychologist, marriage & family therapist, or social worker about the way you were feeling or behaving in the past 3 months?"
Yes
No

What were the reasons for treatment?

Reason for Treatment:	**Yes**	**No**	**Don't know**	**N/A**
Problems telling others about illness	2	1	9	8
Problems coping with other's reaction to illness	2	1	9	8
Anxiety	2	1	9	8
Depression	2	1	9	8
Suicide Threat/Attempt	2	1	9	8
Drugs/Alcohol Abuse	2	1	9	8
Children's behaviors	2	1	9	8
Relationship problems	2	1	9	8
Other (SPECIFY_____)	2	1	9	8

How many times has a health care professional prescribed any medication to help you sleep or cope with emotional or mental health problems you were having?
__ __ times

How many times in the past 3 months has a health care professional prescribed any medication to help you sleep or cope with emotional or mental health problems you were having?
__ __ times

How many times have you ever sought counseling?
__ __ times

Insert timeline reminder here

How many doctor's appointments have you missed in the past three months?
__ __appointments

Why did you miss this appointment?

Why did you miss these appointments?

	YES	NO
Forgot about appointment	1	2
Was afraid to go	1	2
Was too busy to go	1	2
Didn't think it was necessary	1	2
Was too sick to go in	1	2
Didn't think a doctor could help	1	2
Couldn't afford to go	1	2
Figured doctor would not care	1	2
Can always get another appointment	1	2
Will stay sick anyway	1	2
Your privacy would be violated	1	2
Was too hard to get there	1	2
Being with your friends was more important	1	2
Had more fun things to do	1	2
Had to make money	1	2
Was embarrassed to go to an HIV clinic	1	2
Didn't want others to know	1	2
Did not have transportation	1	2
	1	2

If yes, ask: Are there any other reasons that you missed this appointment?

If no, ask: Are there any other reasons that you missed these appointments? (SPECIFY:_____)

When was your last appointment with your doctor or health care provider?

Within the past one month	1
1-3 months ago	2
4-6 months ago	3
7-12 months ago	4
1-2 years ago	5
Over 2 years ago	6

Have you ever been refused medical treatment?

Yes	1
No	2

Were you refused treatment for financial reasons?
Yes
No

Were you refused treatment due to your HIV status?
Yes
No

How often do you inform doctors or other medical staff other than your HIV provider about your HIV status?

Never	1
Rarely	2
Sometimes	3
Most of the time	4
Always	5
Not applicable	8

APPENDIX VIII: MENTAL ADJUSTMENT TO HIV SCALE

Now we will explore your feelings about HIV infection. Please choose the appropriate response for each question based on how you feel at the moment. Thank you for your help.

Scale:
1 = Definitely does not apply to me
2 = Does not apply to me
3 = Applies to me
4 = Definitely applies to me

I have been doing things that I believe will improve my health (e.g., changed my diet)	1	2	3	4
I feel I can't do anything to cheer myself up	1	2	3	4
I feel that problems with my health prevent me from planning ahead	1	2	3	4
I believe that my positive attitude will benefit my health	1	2	3	4
I don't dwell my illness	1	2	3	4
I firmly believe that I will get better	1	2	3	4
I feel that nothing I can do will make any difference	1	2	3	4
I've left it all to my doctors	1	2	3	4
I feel that life is hopeless	1	2	3	4
I have been doing things that I believe will improve my health (e.g., exercise)	1	2	3	4
Since my diagnosis I now realize how precious life is and I'm making the most of it	1	2	3	4
I've put myself in the hands of God	1	2	3	4
I have plans for the future (e.g., holiday, jobs, housing)	1	2	3	4
I worry about the illness getting worse	1	2	3	4
I've had a good life, what's left is a bonus	1	2	3	4
I think my state of mind can make a lot of difference to my health	1	2	3	4
I feel that there is nothing I can do to help myself	1	2	3	4
I try to carry on life as I've always done	1	2	3	4
I would like to make contact with others in the same boat	1	2	3	4
I am determined to put it all behind me	1	2	3	4
I have great difficulty in believing that this happened to me	1	2	3	4
I suffer great anxiety about it	1	2	3	4
I am not very hopeful about the future	1	2	3	4
At the moment I take one day at a time	1	2	3	4
I feel like giving up	1	2	3	4
I try to keep a sense of humor about it	1	2	3	4
Other people worry about me more than I do	1	2	3	4
I think of other people who are worse off	1	2	3	4

I am trying to get as much information as I can about AIDS	1	2	3	4
I feel I can't control what is happening	1	2	3	4
I try to have a very positive attitude	1	2	3	4
I keep quite busy, so I don't have time to think about it	1	2	3	4
I avoid finding out more about it	1	2	3	4
I see my illness as a challenge	1	2	3	4
I feel fatalistic about it	1	2	3	4
I feel completely at a loss about what to do	1	2	3	4
I feel very angry about what has happened to me	1	2	3	4
I really don't believe my blood test result	1	2	3	4
I try to count my blessings	1	2	3	4
I try to fight the illness	1	2	3	4

APPENDIX IX: SELF EFFICACY FOR DISCLOSURE OF HIV STATUS

SelfIntro The following section asks questions about disclosing your HIV status to sex partners. Remember, all of your answers are anonymous.

Selfhot I can disclose my HIV status before having sex even to a really hot new sex partner.

1 = Absolutely sure I cannot
2 = Somewhat sure I cannot
3 = Unsure if I can or cannot
4 = Somewhat sure I can
5 = Absolutely sure I can

SelfHotNeg I can disclose my HIV status before having sex even to a really hot new sex partner who I think might be HIV negative.

1 = Absolutely sure I cannot
2 = Somewhat sure I cannot
3 = Unsure if I can or cannot
4 = Somewhat sure I can
5 = Absolutely sure I can

SelfDepress I can disclose my HIV status before having sex even to a new sex partner when I'm really depressed or upset.

1 = Absolutely sure I cannot
2 = Somewhat sure I cannot
3 = Unsure if I can or cannot
4 = Somewhat sure I can
5 = Absolutely sure I can

SelfPos I can disclose my HIV status before having sex even if my partner did not know I was positive the first time we had sex.

1 = Absolutely sure I cannot
2 = Somewhat sure I cannot
3 = Unsure if I can or cannot
4 = Somewhat sure I can
5 = Absolutely sure I can

SelfWorry I can disclose my HIV status before having sex even if I was worried that my partner wouldn't have sex with me if they knew.

1 = Absolutely sure I cannot
2 = Somewhat sure I cannot
3 = Unsure if I can or cannot
4 = Somewhat sure I can
5 = Absolutely sure I can

SelfTold I can disclose my HIV status before having sex even to a sex partner who hasn't told me their HIV status.

1 = Absolutely sure I cannot
2 = Somewhat sure I cannot
3 = Unsure if I can or cannot
4 = Somewhat sure I can
5 = Absolutely sure I can

APPENDIX X: HIV STIGMA SCALE

StigmaIntro These questions ask about some of the social and emotional aspects of having HIV. There are no right or wrong answers.

This first set of questions asks about some of your experiences, feelings, and opinions as to how people with HIV feel and how they are treated. Please do your best to answer each question.

For each item, choose your answer: strongly disagree, disagree, agree, or strongly agree.

Stigma1 In many areas of my life, no one knows that I have HIV.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

Stigma2 I feel guilty because I have HIV.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

Stigma3 People's attitudes about HIV make me feel worse about myself.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

Stigma4 Telling someone I have HIV is risky.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

StigmaJob People with HIV lose their jobs when their employers find out.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

Stigma5 I work hard to keep my HIV a secret.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

Stigma6 I feel I am not as good a person as others because I have HIV.
1=Strongly agree

2=Agree
3=Disagree
4=Strongly disagree

Stigma7 I never feel ashamed of having HIV.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

StigmaTreat People with HIV are treated like outcasts.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

StigmaDirty Most people believe that a person who has HIV is dirty.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

Stigma8 It is easier to avoid new friendships than worry about telling someone that I have HIV.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

Stigma9 Having HIV makes me feel unclean.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

Stigma10 Since learning I have HIV, I feel set apart and isolated from the rest of the world.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

StigmaDisgust Most people think that a person with HIV is disgusting.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

Stigma11 Having HIV makes me feel that I'm a bad person.
1=Strongly agree
2=Agree

3=Disagree
4=Strongly disagree

StigmaReject Most people with HIV are rejected when others find out.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

Stigma12 I am very careful who I tell that I have HIV.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

StigmaDistant Some people who know I have HIV have grown more distant.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

Stigma13 Since learning I have HIV, I worry about people discriminating against me.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

StigmaUncomfort Most people are uncomfortable around someone with HIV.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

Stigma14 I never feel the need to hide the fact that I have HIV.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

Stigma15 I worry that people may judge me when they learn I have HIV.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

Stigma16 Having HIV in my body is disgusting to me.
1=Strongly agree
2=Agree
3=Disagree

4=Strongly disagree

StigmaIntro2 Many of the items in this next section assume that you have told other people that you have HIV, or that others know. This may not be true for you. If the item refers to something that has not actually happened to you, please imagine yourself in that situation. Then give your answer ("strongly disagree," "disagree," "agree," "strongly agree") based on how you think you would feel or how you think others would react to you.

StigmaHurt I have been hurt by how people reacted to learning I have HIV.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

Stigma17 I worry that people who know I have HIV will tell others.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

StigmaRegret I regret having told some people that I have HIV.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

Stigma18 As a rule, telling others that I have HIV has been a mistake.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

StigmaAvoid Some people avoid touching me once they know I have HIV.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

StigmaCare People I care about stopped calling after learning I have HIV.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

StigmaDeserve People have told me that getting HIV is what I deserve for how I lived my life.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

StigmaClose Some people close to me are afraid others will reject them if it becomes known that I have HIV.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

StigmaChild People don't want me around their children once they know I have HIV.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

StigmaBack People have physically backed away from me when they learn I have HIV.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

StigmaFault Some people act as though it's my fault I have HIV.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

StigmaStop I have stopped socializing with some people because of their reactions to my having HIV.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

StigmaLost I have lost friends by telling them I have HIV.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

Stigma19 I have told people close to me to keep the fact that I have HIV a secret.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

Stigma20 People who know I have HIV tend to ignore my good points.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

Stigma21 People seem afraid of me once they learn I have HIV.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

StigmaFlaw When people learn you have HIV, they look for flaws in your character.
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

The Brief Symptom Inventory-18 (BSI-18) has been redacted. For access to the BSI-18, please visit: http://www.pearsonclinical.com/psychology/products/100000450/brief-symptom-inventory-bsi.html

APPENDIX XII: HEALTH BELIEF MODEL - SELF-EFFICACY FOR SEXUAL DISCUSSION

HBMSDIntro The next section asks about your ability to discuss sex with your sex partner(s).

If you are not currently sexually active, think back to your last sex partner or partners.

HBMSDOtherSex It is hard to ask a sex partner about other people they have had sex with.
1=Strongly Agree
2=Somewhat Agree
3=Somewhat Disagree
4=Strongly Disagree

HBMSDSexMore It is hard to ask someone if they have had sex with more than one person in the last year.
1=Strongly Agree
2=Somewhat Agree
3=Somewhat Disagree
4=Strongly Disagree

HBMSDCondom I am able to discuss the use of condoms with my sex partner.
1=Strongly Agree
2=Somewhat Agree
3=Somewhat Disagree
4=Strongly Disagree

HBSMDAskPriorPart I am able to ask my sex partner how many people they have had sex with before me.
1=Strongly Agree
2=Somewhat Agree
3=Somewhat Disagree
4=Strongly Disagree

HBSMDAnal I am able to ask my sex partner(s) if they have ever had anal sex.
1=Strongly Agree
2=Somewhat Agree
3=Somewhat Disagree
4=Strongly Disagree

HBSMDIVDrug I am able to ask my sex partner(s) if they have ever used IV drugs.
1=Strongly Agree
2=Somewhat Agree
3=Somewhat Disagree
4=Strongly Disagree

HBSMDSexMan I am able to ask my sex partner(s) if they have ever had sex with another man.
1=Strongly Agree

2=Somewhat Agree
3=Somewhat Disagree
4=Strongly Disagree

HBSMDPriorPart I am able to tell my sex partner(s) how many people I have had sex with before him or her.
1=Strongly Agree
2=Somewhat Agree
3=Somewhat Disagree
4=Strongly Disagree

APPENDIX XIII: CONDOM USE SELF-EFFICACY SCALE (CUSES)

CUSESIntro The following questions ask about your feelings about using condoms.

CUSESAbility I feel confident in my ability to put a condom on myself or my partner.
1=Strongly Agree
2=Agree
3=Undecided
4=Disagree
5=Strongly Disagree

CUSESPurchase I feel confident I could purchase condoms without feeling embarrassed.
1=Strongly Agree
2=Agree
3=Undecided
4=Disagree
5=Strongly Disagree

CUSESCarry I feel confident I could remember to carry a condom with me should I need one.
1=Strongly Agree
2=Agree
3=Undecided
4=Disagree
5=Strongly Disagree

CUSESDiscuss I feel confident in my ability to discuss condom usage with any partner I might have.
1=Strongly Agree
2=Agree
3=Undecided
4=Disagree
5=Strongly Disagree

CUSESSuggest I feel confident in my ability to suggest using condoms with a new partner.
1=Strongly Agree
2=Agree
3=Undecided
4=Disagree
5=Strongly Disagree

CUSESUse I feel confident I could suggest using a condom without my partner feeling "diseased".
1=Strongly Agree
2=Agree
3=Undecided
4=Disagree
5=Strongly Disagree

CUSESMaintain I feel confident in my own or my partner's ability to maintain an erection while using a condom.
1=Strongly Agree

2=Agree
3=Undecided
4=Disagree
5=Strongly Disagree

CUSESEmbarrass I would feel embarrassed to put a condom on myself or my partner.
1=Strongly Agree
2=Agree
3=Undecided
4=Disagree
5=Strongly Disagree

CUSESReject If I were to suggest using a condom to a partner, I would feel afraid that he or she would reject me.
1=Strongly Agree
2=Agree
3=Undecided
4=Disagree
5=Strongly Disagree

CUSESUnsure If I were unsure of my partner's feelings about using condoms, I would not suggest using one.
1=Strongly Agree
2=Agree
3=Undecided
4=Disagree
5=Strongly Disagree

CUSESConfident I feel confident in my ability to use a condom correctly.
1=Strongly Agree
2=Agree
3=Undecided
4=Disagree
5=Strongly Disagree

CUSESComfort I would feel comfortable discussing condom use with a potential sexual partner before we ever had any sexual contact (such as hugging, kissing, caressing, etc.)
1=Strongly Agree
2=Agree
3=Undecided
4=Disagree
5=Strongly Disagree

CUSESPersuade I feel confident in my ability to persuade a partner to accept using a condom when we have intercourse.

1=Strongly Agree
2=Agree
3=Undecided

4=Disagree
5=Strongly Disagree

CUSESGrace I feel confident I could gracefully remove and dispose of a condom after we have intercourse.
1=Strongly Agree
2=Agree
3=Undecided
4=Disagree
5=Strongly Disagree

CUSESSucceed If my partner and I were to try to use a condom and did not succeed, I would feel embarrassed to try to use one again (such as not being able to unroll condom, putting it on backwards, or awkwardness).
1=Strongly Agree
2=Agree
3=Undecided
4=Disagree
5=Strongly Disagree

CUSESNoConfid I would not feel confident suggesting using condoms with a new partner because I would be afraid he or she would think I've had a homosexual experience.
1=Strongly Agree
2=Agree
3=Undecided
4=Disagree
5=Strongly Disagree

CUSESNoSTD I would not feel confident suggesting using condoms with a new partner because I would be afraid he or she would think I have a sexually transmitted disease.
1=Strongly Agree
2=Agree
3=Undecided
4=Disagree
5=Strongly Disagree

CUSESSTD I would not feel confident suggesting using condoms with a new partner because I would be afraid he or she would think I thought they had a sexually transmitted disease.
1=Strongly Agree
2=Agree
3=Undecided
4=Disagree
5=Strongly Disagree

CUSESIntercourse I would feel comfortable discussing condom use with a potential partner before we ever engaged in intercourse.
1=Strongly Agree
2=Agree
3=Undecided

4=Disagree
5=Strongly Disagree

CUSESIncorp I feel confident in my ability to incorporate putting a condom on myself or my partner into foreplay.
1=Strongly Agree
2=Agree
3=Undecided
4=Disagree
5=Strongly Disagree

CUSESMood I feel confident that I could use a condom with a partner without "breaking the mood."
1=Strongly Agree
2=Agree
3=Undecided
4=Disagree
5=Strongly Disagree

CUSESQuick I feel confident in my ability to put a condom on myself or my partner quickly.
1=Strongly Agree
2=Agree
3=Undecided
4=Disagree
5=Strongly Disagree

CUSESReduce I feel confident I could use a condom during intercourse without reducing any sexual sensations.
1=Strongly Agree
2=Agree
3=Undecided
4=Disagree
5=Strongly Disagree

CUSESDrink I feel confident that I would remember to use a condom even after I have been drinking.
1=Strongly Agree
2=Agree
3=Undecided
4=Disagree
5=Strongly Disagree

CUSESHigh I feel confident that I would remember to use a condom even if I were high.
1=Strongly Agree
2=Agree
3=Undecided
4=Disagree
5=Strongly Disagree

CUSESNecessary If my partner didn't want to use a condom during intercourse, I could easily convince him or her that it was necessary to do so.
1=Strongly Agree
2=Agree
3=Undecided
4=Disagree
5=Strongly Disagree

CUSESSuccess I feel confident that I could use a condom successfully.
1=Strongly Agree
2=Agree
3=Undecided
4=Disagree
5=Strongly Disagree

CUSESHeat I feel confident I could stop to put a condom on myself or my partner even in the heat of passion.
1=Strongly Agree
2=Agree
3=Undecided
4=Disagree
5=Strongly Disagree

APPENDIX XIV: HIV/STD KNOWLEDGE QUESTIONNAIRE

STDIntro The following statements are about STDs (Sexually Transmitted Diseases) and HIV. Please indicate whether you think the statement is "true" or "false". If you aren't sure, choose "don't know".

STDDouche Douching after sex helps protect you from STDs.
True
False
Don't Know

STDCut You can't get the AIDS virus through a cut in your skin.
True
False
Don't Know

STDTell You can't always tell if your partner has as STD.
True
False
Don't Know

STDPre Pre-ejaculatory fluids (pre-cum) carry HIV.
True
False
Don't Know

STDSick People who have HIV generally feel sick right away.
True
False
Don't Know

STDShare You can't get HIV by sharing knives and forks or a bathroom with a person who has HIV.
True
False
Don't Know

STDUntreat An untreated STD can possibly result in being unable to have children.
True
False
Don't Know

STDCondom Condoms with spermicide will protect you from most STDs.
True
False
Don't Know

STDSpread Women can spread STDs to men when they don't use condoms.
True

False
Don't Know

STDBirthCntrl If a woman uses birth control pills, it lowers her risk for getting HIV.
True
False
Don't Know

STDHIVRisk Having an STD puts you at greater risk for getting HIV.
True
False
Don't Know

STDKiss If a person has HIV, it is still safe to kiss them on the lips, as you would kiss a friend or relative.
True
False
Don't Know

STDPrevent The most effective way to prevent the spread of HIV is abstinence from sex.
True
False
Don't Know

STDSheepskin Sheep skin condoms are better than latex condoms for preventing HIV.
True
False
Don't Know

STDOil Using oil based lubricants such as Vaseline or Crisco with condoms will reduce the risk of getting HIV.
True
False
Don't Know

STDCure All STDs, except for HIV, can be cured with antibiotics.
True
False
Don't Know

APPENDIX XV: ASSIST V3.0

AssistIntro The following questions are about your experiences using alcohol, tobacco products, and other drugs. The questions will concern your experience of using these substances across your lifetime and in the past three months. These substances can be smoked, swallowed, snorted, inhaled, injected, or taken in the form of pills.

Some of the substances may be prescribed by a doctor (like amphetamines, sedatives, pain medications). For this interview, we will not record medications that are used as prescribed by your doctor. However, if you have taken such medications for reasons other than prescription, or taken them more frequently or at higher doses than prescribed, please let me know. While we are also interested in knowing about your use of various illicit drugs, please be assured that information on such use will be treated as strictly anonymous.

Insert timeline reminder here

Assist1a In your life, have you ever used tobacco products (cigarettes, chewing tobacco, cigars, etc.)?
Yes
No ***(Skip to Assist2a)***

Assist2a In your life, have you ever used alcoholic beverages (beer, wine, spirits, etc.)?
Yes
No ***(Skip to Assist3a)***

Assist3a In your life, have you ever used cannabis (marijuana, pot, grass, hash, etc.)?
Yes
No ***(Skip to Assist4a)***

Assist5a In your life, have you ever used amphetamine type stimulants (speed, diet pills, ecstasy, etc.)? This includes crystal methamphetamine ("meth," "ice," "crystal," "glass," and "tina").
Yes
No ***(Skip to Assist6a)***

APPENDIX XVI: SOCIAL SUPPORT FOR ADOLESCENTS SCALE (SSAS)

SSASIntro Now, we are going to ask you about various people that offer support when you are having problems. Please answer each of the questions for each group of people and the type of support they offer you.

SSASPersonal When you go to talk about a personal problem, how helpful is each of the following people?

SSASPersonalFriend Group of close friends

Not at all
Somewhat
A great deal

SSASPersonalAge People your age

Not at all
Somewhat
A great deal

SSASPersonalFather Father

Not at all
Somewhat
A great deal

SSASPersonalMother Mother

Not at all
Somewhat
A great deal

SSASPesonalSib Sisters/brothers

Not at all
Somewhat
A great deal

SSASPersonalPrincipal Principal/ teacher/professor

Not at all
Somewhat
A great deal

SSASPersonalMed Medical provider (doctor/nurse)

Not at all
Somewhat
A great deal

SSASPersonalHealth Mental health provider (psychologist/social worker)

Not at all
Somewhat
A great deal

SSASMoney When you need money and other things, how helpful is each of the following people?

SSASMoneyFriends Group of close friends

Not at all
Somewhat
A great deal

SSASMoneyAge People your age

Not at all
Somewhat
A great deal

SSASMoneyFather Father

Not at all
Somewhat
A great deal

SSASMoneyMother Mother

Not at all
Somewhat
A great deal

SSASMoneySib Sisters/brothers

Not at all
Somewhat
A great deal

SSASMoneyPrincipal Principal/ teacher/professor

Not at all
Somewhat
A great deal

SSASMoneyMed Medical provider (doctor/nurse)

Not at all
Somewhat
A great deal

SSASMoneyHealth Mental health provider (psychologist/social worker)

Not at all
Somewhat
A great deal

SSASFun How much do you have fun with each of the following people?

SSASFunFriend Group of close friends

None
Some
A lot

SSASFunAge People your age

Not at all
Somewhat
A great deal

SSASFunFather Father

Not at all
Somewhat
A great deal

SSASFunMother Mother

Not at all
Somewhat
A great deal

SSASFunSib Sisters/brothers

Not at all
Somewhat
A great deal

SSASFunPrincipal Principal/ teacher/professor

Not at all
Somewhat

A great deal

SSASFunMed Medical provider (doctor/nurse)

Not at all
Somewhat
A great deal

SSASFunHealth Mental health provider (psychologist/social worker)

Not at all
Somewhat
A great deal

APPENDIX XVII: NUTRITION AND EXERCISE QUESTIONS

These next statements are about general health topics. Please read each statement carefully and indicate whether you strongly agree, agree, disagree, or strongly disagree by placing a check in the appropriate box. Check one box for each statement.

		Strongly agree	Agree	Disagree	Strongly disagree
1.	In a typical day, adolescents should eat a variety of vegetables, especially dark-green and red and orange vegetables and beans and peas.	☐	☐	☐	☐
2.	Dairy products, such as yogurt and milk, provide calcium for building bones and protein for building muscle.	☐	☐	☐	☐
3.	The nutritional needs of adolescents are the same as when they were young children.	☐	☐	☐	☐
4.	Aerobic exercise burns calories and builds endurance.	☐	☐	☐	☐
5.	Overweight people are not at risk for high blood pressure.	☐	☐	☐	☐
6.	One should increase physical activity and reduce time spent in sedentary behaviors.	☐	☐	☐	☐
7.	Over half of adolescents try smoking cigarettes.	☐	☐	☐	☐
8.	Young people who smoke cigarettes can stop whenever they want.	☐	☐	☐	☐

		Strongly agree	Agree	Disagree	Strongly disagree
9.	Smoking when you are pregnant harms the unborn child.	☐	☐	☐	☐
10.	Amenorrhea, Dysmenorrhea, and Abnormal uterine bleeding are some of the most common problems women have had with their period.	☐	☐	☐	☐
11.	Testicular cancer is the most common cancer among males aged 15 to 34 year.	☐	☐	☐	☐
12.	Decision making is not affected by alcohol and other drugs.	☐	☐	☐	☐
13.	Smoking marijuana (weed) can clog air sacs and lungs, causing lung infection and bronchitis.	☐	☐	☐	☐
14.	Type 1 diabetes most often occurs in people younger than 30 years and must be controlled by injecting insulin or by using an insulin pump.	☐	☐	☐	☐
15.	People with certain conditions in their or their family's health history are more likely to develop type 2 diabetes.	☐	☐	☐	☐
16.	Cardiovascular disease (CVD) is the leading cause of death in the United States. It causes more than half of all deaths or more than 1.2 million deaths annually.	☐	☐	☐	☐
17.	High blood pressure—also called hypertension—puts you at risk for heart disease.	☐	☐	☐	☐
18.	Physical activity also helps people control their blood glucose (sugar).	☐	☐	☐	☐
19.	Three in 10 adults drink at levels that put them at risk for alcoholism, liver	☐	☐	☐	☐

disease, and other problems.

20.	Gen Next are more likely than older adults to say internet makes it easier for them to make new friends and help them stay close to old friends and family.	☐	☐	☐	☐

APPENDIX XVIII: NATIONAL YOUTH RISK BEHAVIOR SURVEY

This survey is about health behavior. The next 5 questions ask about body weight.

How do you describe your weight?
A. Very underweight
B. Slightly underweight
C. About the right weight
D. Slightly overweight
E. Very overweight

Which of the following are you trying to do about your weight?
A. Lose weight
B. Gain weight
C. Stay the same weight
D. I am not trying to do anything about my weight

During the past 30 days, did you go without eating for 24 hours or more (also called fasting) to lose weight or to keep from gaining weight?
A. Yes
B. No

During the past 30 days, did you take any diet pills, powders, or liquids without a doctor's advice to lose weight or to keep from gaining weight? (Do not include meal replacement products such as Slim Fast.)
A. Yes
B. No

During the past 30 days, did you vomit or take laxatives to lose weight or to keep from gaining weight?
A. Yes
B. No

The next 9 questions ask about food you ate or drank during the past 7 days. Think about all the meals and snacks you had from the time you got up until you went to bed. Be sure to include food you ate at home, at school, at restaurants, or anywhere else.

During the past 7 days, how many times did you drink 100% fruit juices such as orange juice, apple juice, or grape juice? (Do not count punch, Kool-Aid, sports drinks, or other fruit-flavored drinks.)
A. I did not drink 100% fruit juice during the past 7 days
B. 1 to 3 times during the past 7 days
C. 4 to 6 times during the past 7 days
D. 1 time per day
E. 2 times per day
F. 3 times per day
G. 4 or more times per day

During the past 7 days, how many times did you eat fruit? (Do not count fruit juice.)
A. I did not eat fruit during the past 7 days
B. 1 to 3 times during the past 7 days
C. 4 to 6 times during the past 7 days
D. 1 time per day

E. 2 times per day
F. 3 times per day
G. 4 or more times per day

During the past 7 days, how many times did you eat green salad?
A. I did not eat green salad during the past 7 days
B. 1 to 3 times during the past 7 days
C. 4 to 6 times during the past 7 days
D. 1 time per day
E. 2 times per day
F. 3 times per day
G. 4 or more times per day

During the past 7 days, how many times did you eat potatoes? (Do not count french fries, fried potatoes, or potato chips.)
A. I did not eat potatoes during the past 7 days
B. 1 to 3 times during the past 7 days
C. 4 to 6 times during the past 7 days
D. 1 time per day
E. 2 times per day
F. 3 times per day
G. 4 or more times per day

During the past 7 days, how many times did you eat carrots?
A. I did not eat carrots during the past 7 days
B. 1 to 3 times during the past 7 days
C. 4 to 6 times during the past 7 days
D. 1 time per day
E. 2 times per day
F. 3 times per day
G. 4 or more times per day

During the past 7 days, how many times did you eat other vegetables? (Do not count green salad, potatoes, or carrots.)
A. I did not eat other vegetables during the past 7 days
B. 1 to 3 times during the past 7 days
C. 4 to 6 times during the past 7 days
D. 1 time per day
E. 2 times per day
F. 3 times per day
G. 4 or more times per day

During the past 7 days, how many times did you drink a can, bottle, or glass of soda or pop, such as Coke, Pepsi, or Sprite? (Do not count diet soda or diet pop.)
A. I did not drink soda or pop during the past 7 days
B. 1 to 3 times during the past 7 days
C. 4 to 6 times during the past 7 days
D. 1 time per day
E. 2 times per day
F. 3 times per day
G. 4 or more times per day

During the past 7 days, how many glasses of milk did you drink? (Count the milk you drank in a glass or cup, from a carton, or with cereal. Count the half pint of milk served at school as equal to one glass.)
A. I did not drink milk during the past 7 days
B. 1 to 3 glasses during the past 7 days
C. 4 to 6 glasses during the past 7 days
D. 1 glass per day
E. 2 glasses per day
F. 3 glasses per day
G. 4 or more glasses per day

During the past 7 days, on how many days did you eat breakfast?
A. 0 days
B. 1 day
C. 2 days
D. 3 days
E. 4 days
F. 5 days
G. 6 days
H. 7 days

The next 4 questions ask about physical activity.

During the past 7 days, on how many days were you physically active for a total of at least 60 minutes per day? (Add up all the time you spent in any kind of physical activity that increased your heart rate and made you breathe hard some of the time.)
A. 0 days
B. 1 day
C. 2 days
D. 3 days
E. 4 days
F. 5 days
G. 6 days
H. 7 days

On how many of the past 7 days did you do exercises to strengthen or tone your muscles, such as push-ups, sit-ups, or weight lifting?
A. 0 days
B. 1 day
C. 2 days
D. 3 days
E. 4 days
F. 5 days
G. 6 days
H. 7 days

On an average school day, how many hours do you watch TV?
A. I do not watch TV on an average school day
B. Less than 1 hour per day
C. 1 hour per day
D. 2 hours per day

E. 3 hours per day
F. 4 hours per day
G. 5 or more hours per day

On an average school day, how many hours do you play video or computer games or use a computer for something that is not school work? (Include activities such as Xbox, PlayStation, Nintendo DS, iPod touch, Facebook, and the Internet.)
A. I do not play video or computer games or use a computer for something that is not school work
B. Less than 1 hour per day
C. 1 hour per day
D. 2 hours per day
E. 3 hours per day
F. 4 hours per day
G. 5 or more hours per day

The next questions ask about other health-related topics.

On an average night, how many hours of sleep do you get?
A. 4 or less hours
B. 5 hours
C. 6 hours
D. 7 hours
E. 8 hours
F. 9 hours
G. 10 or more hours

APPENDIX XIX: SECONDARY PREVENTION WORKING GROUP

SECTION I. SEXUAL ACTIVITY

The following questions are about times that you had different types of sex because you wanted to, not because you were forced or pressured to have sex. Please answer the following questions and remember to only think about the times you had the different types of sex because you wanted to. Remember that your answers are anonymous.

Let's briefly go over the definitions of some terms so that you understand what is being asked.

When I say vaginal sex, I mean when a man or boy puts his penis into a woman's or girl's vagina.

When I say oral sex, I mean when one partner puts her/his mouth on the other person's penis or vagina.

When I say receptive anal sex, I mean when a man or boy puts his penis into your anus or butt.

When I say insertive anal sex, I mean when you put your penis into the anus or butt of your partner.

Now I'd like you to take a moment to think back about your sex life during the past 3 months— that is, since [month fill]. I'm going to ask you some questions about the sex you have had during that period.

[FOR WOMEN ONLY: Sections I.A. & I.B.]

I.A. [WOMAN WITH MAN SEX]

During the past 3 months, how many male partners have you had sexual contact with (oral, anal, or vaginal)? |____|____|____|
[If "0" skip to Section I.B.]

Of these males, how many were known to be HIV positive? |____|____|____| [If "0" skip to Section I.A.2]

I.A.1. With your known HIV positive male partners during the past 3 months:

How many times have you performed oral sex on a male WITHOUT a condom? |____|____|____|

How many times have you performed oral sex on a male WITH a condom? |____|____|____|

How many times have you received oral sex from a male WITHOUT a barrier (dental dam)?
|____|____|____|

How many times have you received oral sex from a male WITH a barrier (dental dam)?|____|____|____|

How many times have you had vaginal sex with a male partner WITHOUT a condom? |____|____|____|

How many times have you had vaginal sex with a male partner WITH a condom? |____|____|____|

How many times have you had anal sex with a male WITHOUT a condom? |____|____|____|

How many times have you had anal sex with a male WITH a condom? |____|____|____|

I.A.2. During the past 3 months, how many of your male partners were HIV negative or of unknown HIV status? |____|____|____| [If "0" skip to Section I.B]

With your HIV negative and HIV unknown status male partners during the past 3 months:

How many times have you performed oral sex on a male partner WITHOUT a condom?
|____|____|____|

How many times have you performed oral sex on a male partner WITH a condom? |____|____|____|

How many times have you received oral sex from a male WITHOUT a barrier (dental dam)?
|____|____|____|

How many times have you received oral sex from a male WITH a barrier (dental dam)?|____|____|____|

How many times have you had vaginal sex with a male partner WITHOUT a condom? |____|____|____|

How many times have you had vaginal sex with a male partner WITH a condom? |____|____|____|

How many times have you had anal sex with a male partner WITHOUT a condom? |____|____|____|

How many times have you had anal sex with a male partner WITH a condom? |____|____|____|

I.B. [WOMAN WITH WOMAN SEX]

I.B.1. During the past 3 months, how many female partners have you had sexual contact with? |____|____|____| [If "0" skip to Section II]

Of these females, how many were known to be HIV positive? |____|____|____| [If "0" skip to Section I.B.2]

With your known HIV positive female partners during the past 3 months:

How many times have you performed oral sex on a female partner WITHOUT a barrier (dental dam)?
|____|____|____|

How many times have you performed oral sex on a female partner WITH a barrier (dental dam)?
|____|____|____|

How many times have you received oral sex from a female WITHOUT a barrier (dental dam)?
|____|____|____|

How many times have you received oral sex from a female WITH a barrier (dental dam)?
|____|____|____|

How many times have you and a female partner took turns with sex toys (e.g., dildos or penetration toys) in your vaginas or asses WITHOUT washing them (or putting fresh condoms on them) in between?

|____|____|____|

How many times have you and a female partner took turns with sex toys (e.g., dildos or penetration toys) in your vaginas or asses AND you washed them (or put fresh condoms on them) in between?
|____|____|____|

I.B.2. During the past 3 months, how many of your female partners were HIV negative or of unknown HIV status? |____|____|____| [If "0" skip to Section II]

With your HIV negative and HIV unknown status female partners during the past 3 months:

How many times have you performed oral sex on a female partner WITHOUT a barrier (dental dam)?
|____|____|____|

How many times have you performed oral sex on a female partner WITH a barrier (dental dam)?
|____|____|____|

How many times have you received oral sex from a female WITHOUT a barrier (dental dam)?
|____|____|____|

How many times have you received oral sex from a female WITH a barrier (dental dam)?
|____|____|____|

How many times have you and a female partner took turns with sex toys (e.g., dildos or penetration toys) in your vaginas or asses WITHOUT washing them (or putting fresh condoms on them) in between?
|____|____|____|

How many times have you and a female partner took turns with sex toys (e.g., dildos or penetration toys) in your vaginas or asses AND you washed them (or put fresh condoms on them) in between?
|____|____|____|

[FOR MEN ONLY: Sections I.C. & I.D.]

I.C. [MAN WITH WOMAN SEX]

During the past 3 months, how many female partners have you had sexual contact with (oral, anal or vaginal)? |____|____|____| [If "0" skip to Section I.D.]

Of these females, how many were known to be HIV positive? |____|____|____| [If "0" skip to Section I.C.2.]

With your known HIV positive female partners during the past 3 months:

How many times did you perform oral sex on a female partner WITHOUT a barrier (dental dam)?
|____|____|____|

How many times did you perform oral sex on a female partner WITH a barrier (dental dam)?
|____|____|____|

How many times did you receive oral sex from a female WITHOUT a condom? |____|____|____|

How many times did you receive oral sex from a female WITH a condom? |____|____|____|

How many times did you have vaginal sex with a female partner WITHOUT a condom?
|____|____|____|

How many times did you have vaginal sex with a female partner WITH a condom on? |____|____|____|

How many times did you have anal sex with a female partner WITHOUT a condom? |____|____|____|

How many times did you have anal sex with a female partner WITH a condom on? |____|____|____|

I.C.2. During the past 3 months, how many of your female partners were HIV negative or of unknown HIV status? |____|____|____| [If "0" skip to Section I.D.]

With your HIV negative and HIV unknown status female partners during the past 3 months:

How many times did you perform oral sex on a female partner WITHOUT a barrier (dental dam)?
|____|____|____|

How many times did you perform oral sex on a female partner WITH a barrier (dental dam)?
|____|____|____|

How many times did you receive oral sex from a female WITHOUT a condom? |____|____|____|

How many times did you receive oral sex from a female WITH a condom? |____|____|____|

How many times did you have vaginal sex with a female partner WITHOUT a condom?
|____|____|____|

How many times did you have vaginal sex with a female partner WITH a condom on? |____|____|____|

How many times did you have anal sex with a female partner WITHOUT a condom? |____|____|____|

How many times did you have anal sex with a female partner WITH a condom on? |____|____|____|

I.D. [MAN WITH MAN SEX]

I.D.1. During the past 3 months, how many male partners have you had sexual contact with (oral or anal)?
|____|____|____| [If "0" skip to Section II.]

Of these males, how many were known to be HIV positive? |____|____|____| [If "0" skip to Section I.D.2.]

With your known HIV positive male partners during the past 3 months:

How many times did you perform oral sex on a male partner WITHOUT a condom? |____|____|____|

How many times did you perform oral sex on a male partner WITH a condom? |____|____|____|

How many times did you receive oral sex from a male WITHOUT a condom? |____|____|____|

How many times did you receive oral sex from a male WITH a condom? |____|____|____|

How many times did you have insertive anal sex with male partner WITHOUT a condom?
|____|____|____|

How many times did you have insertive anal sex with a male partner WITH a condom? |____|____|____|

How many times did you have receptive anal sex with male partner WITHOUT a condom?
|____|____|____|

How many times did you have receptive anal sex with a male partner WITH a condom?
|____|____|____|

I.D.2. During the past 3 months, how many of your male partners were HIV negative or of unknown HIV status? |____|____|____| [If "0" skip to Section II]

With your HIV negative and HIV unknown status male partners during the past 3 months:

How many times did you perform oral sex on a male partner WITHOUT a condom? |____|____|____|

How many times did you perform oral sex on a male partner WITH a condom? |____|____|____|

How many times did you receive oral sex from a male WITHOUT a condom? |____|____|____|

How many times did you receive oral sex from a male WITH a condom? |____|____|____|

How many times did you have insertive anal sex with male partner WITHOUT a condom?
|____|____|____|

How many times did you have insertive anal sex with a male partner WITH a condom? |____|____|____|

How many times did you have receptive anal sex with male partner WITHOUT a condom?
|____|____|____|

How many times did you have receptive anal sex with a male partner WITH a condom?
|____|____|____|

SECTION II. DRUGS/ALCOHOL AND SEX

Introduction
The next group of questions asks about times when you have or have not used condoms with either male or female partners.

II.A. After drinking alcohol, did you have unprotected vaginal or anal sex even though you had intended to use a condom in the past 3 months? ☐ No ☐ Yes [If YES, answer II.A.1. & II.A.2.]

II.A.1. How often has this happened in the past 3 months with an HIV positive partner? |____|____| times

II.A.2. How often has this happened in the past 3 months with an HIV negative or unknown partner? |____|____| times

II.B. After smoking marijuana, did you have unprotected vaginal or anal sex even though you had intended to use a condom in the past 3 months? ☐ No ☐ Yes [If YES, answer II.B.1. & II.B.2.]

II.B.1. How often has this happened in the past 3 months with an HIV positive partner? |____|____| times

II.B.2. How often has this happened in the past 3 months with an HIV negative or unknown partner? |____|____| times

II.C. After using other drugs besides alcohol and marijuana, did you have unprotected vaginal or anal sex with an HIV positive partner even though you had intended to use a condom in the past 3 months? ☐ No ☐ Yes [If YES, answer II.C.1. & II.C.2.]

II.C.1. How often has this happened in the past 3 months with an HIV positive partner? |____|____| times

II.C.2. How often has this happened in the past 3 months with an HIV negative or unknown partner? |____|____| times

SECTION III. SEROSORTING, STRATEGIC POSITIONING, VIRAL LOAD

The following questions ask for your opinions regarding a number of statements about sexual activity and condom use. For the following items, please circle the number between 1 and 4 that stands for how much you agree or disagree with each statement. Circling a "4" means that you strongly agree with the statement and circling "1" means that you strongly disagree with the statement. You can also use the numbers between 1 and 4. For example, if you agree, but not real strongly, you should answer "3," and if you disagree, but not real strongly, then answer "2."

Answer options for all questions:

1=Strongly Disagree
2=Disagree
3=Agree
4=Strongly Agree

1. If my viral load is low or undetectable I am less likely to infect another person with HIV if I have unprotected sex (sex without a condom or barrier).

2. I practice safer sex (sex with a condom or barrier) less often now because new medical treatments for HIV/AIDS have come along.

3. I am less concerned about using condoms with a partner who is also HIV positive.

4. I am more concerned about using condoms with HIV negative/unknown status partners when my viral load is detectable.

5. A partner who doesn't seem interested in using condoms is probably also HIV positive.

6. A partner who doesn't seem interested in using condoms probably thinks he/she is not at risk for HIV.

7. I have not told some of my sex partners that I am HIV positive to avoid being rejected.

8. I purposely look for other HIV positive people to have sex with.

9. It is difficult for women to pass HIV to men during unprotected sex.

10. It is difficult for an HIV positive man to transmit HIV if he is the bottom (the one who receives the penis in his butt/anus).

11. I will have oral sex with a partner instead of either vaginal or anal sex in order to reduce the risk of infecting another person with HIV.

APPENDIX XX: HIV-HEALTH RELATED QUALITY OF LIFE (HIV-HRQOL)

LifeIntro1 Read each statement carefully. Please indicate how satisfied or dissatisfied you currently are with the aspect of your life described in the statement. Choose the answer that best describes how you feel. There is no right or wrong answers to these questions. We are interested in your opinion.

Life1 How satisfied are you with the amount of time it takes to manage your HIV?
Very satisfied
Moderately satisfied
Neither satisfied nor dissatisfied
Moderately dissatisfied
Very dissatisfied

Life2 How satisfied are you with the amount of time you spend getting check ups?
Very satisfied
Moderately satisfied
Neither satisfied nor dissatisfied
Moderately dissatisfied
Very dissatisfied

Life4 How satisfied are you with your knowledge about your HIV?
Very satisfied
Moderately satisfied
Neither satisfied nor dissatisfied
Moderately dissatisfied
Very dissatisfied

Life5 How satisfied are you with your social relationships?
Very satisfied
Moderately satisfied
Neither satisfied nor dissatisfied
Moderately dissatisfied
Very dissatisfied

Life6 How satisfied are you with your sex life?
Very satisfied
Moderately satisfied
Neither satisfied nor dissatisfied
Moderately dissatisfied
Very dissatisfied

Life7 How satisfied are you with your work, school, and household activities?
Very satisfied
Moderately satisfied
Neither satisfied nor dissatisfied
Moderately dissatisfied
Very dissatisfied

Life8 How satisfied are you with the appearance of your body?
Very satisfied
Moderately satisfied
Neither satisfied nor dissatisfied
Moderately dissatisfied
Very dissatisfied

Life9 How satisfied are you in general?
Very satisfied
Moderately satisfied
Neither satisfied nor dissatisfied
Moderately dissatisfied
Very dissatisfied

LifeIntro2 Please indicate how often the following events happen to you.

Life13 How often do you feel physically ill?
Never
Very seldom
Sometimes
Often
All the time

Life14 How often does your HIV interfere with your family life?
Never
Very seldom
Sometimes
Often
All the time

Life18 How often do you miss work, school, or household duties because of your HIV?
Never
Very seldom
Sometimes
Often
All the time

Life20 How often are you teased because you have HIV?
Never
Very seldom
Sometimes
Often
All the time

Life21 How often do you find that your HIV prevents you from participating in school activities (for example, being active in a school play, being on a sports team, being in a school band, etc.)?
Never
Very seldom

Sometimes
Often
All the time

Life22 How often do you feel that your HIV is limiting your career or what you will be able to do in the future?
Never
Very seldom
Sometimes
Often
All the time

Life24 How often do you find that close family members (for example, brothers, sisters, cousins) tease you about your HIV?
Never
Very seldom
Sometimes
Often
All the time

LifeIntro4 Please indicate how often the following events happen to you. If the question is not relevant to you, choose "Does not apply".

Life25 How often do you worry about whether you will get married?
Never
Very seldom
Sometimes
Often
All the time
Does not apply

Life26 How often do you worry about whether you will have children?
Never
Very seldom
Sometimes
Often
All the time
Does not apply

Life27 How often do you worry about whether you will not get a job you want?
Never
Very seldom
Sometimes
Often
All the time
Does not apply

Life28 How often do you worry about whether you will be able to complete your education?
Never

Very seldom
Sometimes
Often
All the time
Does not apply

Life29 How often do you worry about whether you will miss school or work?
Never
Very seldom
Sometimes
Often
All the time
Does not apply

Life30 How often do you worry about whether you will be able to take a vacation or a trip?
Never
Very seldom
Sometimes
Often
All the time
Does not apply

Life31 How often do you worry that your body looks different because you have HIV?
Never
Very seldom
Sometimes
Often
All the time
Does not apply

Life32 How often do you worry that because of your HIV you are behind in terms of dating, going to parties, and keeping up with your friends?
Never
Very seldom
Sometimes
Often
All the time
Does not apply

APPENDIX XXI: PARTICIPANT SESSION EVALUATION FORM

Please fill out the following information about the session that you just participated in. This information will be helpful in improving the session.

DATE: _____

	Strongly Agree	Agree	Disagree	Strongly Disagree
1. I learned a lot from this session.	**1**	**2**	**3**	**4**
2. I will be able to apply what I learned from this session in my life.	**1**	**2**	**3**	**4**
3. I was given an opportunity to participate and discuss information with others.	**1**	**2**	**3**	**4**
4. The session was well organized.	**1**	**2**	**3**	**4**
5. The topic of this session was interesting.	**1**	**2**	**3**	**4**
6. The presenter(s) stimulated my interest in the material.	**1**	**2**	**3**	**4**
7. The topic of this session was relevant to my life.	**1**	**2**	**3**	**4**
8. The session was enjoyable.	**1**	**2**	**3**	**4**
9. I would recommend this session to others.	**1**	**2**	**3**	**4**
10. I felt comfortable participating in this session.	**1**	**2**	**3**	**4**

11. What activities did you liked the most from today's session? Please write what about those activities you liked the most.

12. What activities from today's session did you not like? Please write about those activities you did not like.

13. What would you change about this session?

APPENDIX XXII: STD QUESTIONS

STIIntro "These next statements are about your sexual health. Please select the responses as honestly as you can."

LastSTDTest "When was the last time you had testing for a sexually transmitted disease (STD or STI)?" LastSTDTest.wav

1 "Within the last month"…….	LastSTDTest-1.wav
2 "Within the last 2-6 months"…….	LastSTDTest-2.wav
3 "Within the last 6-12 months"……..	LastSTDTest-3.wav
4 "More than a year ago"…….	LastSTDTest-4.wav

STDEverKnow "Have you ever been told you had a sexually transmitted disease (STD or STI) like Chlamydia, herpes or gonorrhea?" EverKnowSTD.wav

1 "Yes"……..	Yes.wav
2 "No"……	No.wav (skip to STDPartner)

STDWhich "Which sexually transmitted diseases were you told you had? Check all that apply." WhichSTD.wav

1 "Herpes/HSV-2"……	WhichSTD-1.wav
2 "Gonorrhea"…….	WhichSTD-2.wav
3 "Chlamydia"…….	WhichSTD-3.wav
4 "Trichomonas"…….	WhichSTD-4.wav
5 "Syphilis"……..	WhichSTD-5.wav
6 "Yeast"……..	WhichSTD-6.wav
7 "Genital warts"…….	WhichSTD-7.wav
8 "Abnormal pap smear"……	WhichSTD-8.wav
9 "Positive HPV test"…….	WhichSTD-9.wav
10 "Other"……	WhichSTD-10.wav
11 "Can't remember name"……	WhichSTD-11.wav

STDPartner "Have you ever been told that one of your sexual partners had a sexually transmitted disease (STD)?" PartnerSTD.wav

1 "Yes"……..	Yes.wav
2 "No"……	No.wav

APPENDIX XXIII: INTENTION TO ADHERE TO HIV TREATMENT

	Strongly agree	Agree	Somewhat agree	Somewhat Disagree	disagree	Strongly disagree
1. Coming regularly to my HIV clinic appointments is good for my health.						
2. My treatment plan for HIV will make a big difference in keeping my HIV infection under control.						
3. HIV medications help to control HIV disease.						
4. If HIV medications are prescribed, it is important to take the medications everyday to control HIV infections.						
5. Not taking HIV medications every day affects how well the HIV treatment works.						
6. An HIV patient who is feeling well can safely stop taking HIV medications.						
7. An HIV infected person who follows recommended care for HIV can expect to live long.						
8. There is a lot I can do to control my HIV infection.						
9. What I do can determine whether my HIV infection gets better or worse.						
10. My actions will have no effect on the outcome of my HIV infection.						

APPENDIX XXIV: PARTICIPANT ACCEPTABILITY QUESTIONNAIRE

PAQIntro "These next statements are about the study sessions you participated in. Please read each statement carefully and indicate whether you strongly agree, agree, disagree, or strongly disagree by tapping on the appropriate answer. Please select the responses as honestly as you can."

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
The information provided in the sessions was useful.	1	2	3	4	5
I am likely to use information that I learned in the program to make changes in my life.	1	2	3	4	5
Information given in the sessions can easily be applied to real life.	1	2	3	4	5
It was difficult to follow the information presented in each session.	1	2	3	4	5
I felt comfortable talking to the group leaders.	1	2	3	4	5
The program addressed issues faced by young people like me.	1	2	3	4	5
The examples used by the interventionists were not relevant.	1	2	3	4	5
The interventionists seemed to be well-informed.	1	2	3	4	5
I would recommend this program to my friends.	1	2	3	4	5
The material presented in the program was easy to understand.	1	2	3	4	5
The interventionists were easy to understand.	1	2	3	4	5
The handouts and other written materials were difficult to read.	1	2	3	4	5
My friends would participate in this program if offered.	1	2	3	4	5
Nine sessions were too many sessions.	1	2	3	4	5
This is a program that I will recommend to my friends.	1	2	3	4	5
How could we improve this program? _____ _____					

_____
_____

What topics do you think would be helpful to add to the program?
_____
_____
_____
_____

	Very difficult	Moderately Difficult	Somewhat Difficult	Slightly Difficult	Not difficult at all
How hard was it to keep appointment sessions?	5	4	3	2	1

What were some things that made it difficult to attend the sessions? "Check all those that apply"

	YES	NO
I didn't have transportation	1	2
I was tired.	1	2
I was in another city.	1	2

If other please specify: (open ended)

What are some things that we can do to make it easier for someone to attend their sessions? Please list as many as you can think of.
_____
_____
_____

APPENDIX XXV: INTERVENTION GROUP ENVIRONMENT SCALE

GESIntro "These next statements are about your experience with the study sessions you participated in. Please read each statement carefully and indicate whether you strongly agree, agree, disagree, or strongly disagree by selecting the appropriate answer."

Response options for items: 4-point Likert scale, with "strongly disagree" (1), "somewhat disagree" (2), "somewhat agree" (3), and "strongly agree" (4) as the response options.

Item Wording
Cohesiveness subscale
1. Group members feel a sense of belongingness to the group.
2. Group member feel close to each other.
3. The group is a good place to make friends.
4. Group members show that they care for one another. [a]
5. Group members are committed to the group. [a]
6. Group members can understand what others in the group are going through. [a]
7. Group members are supportive of one another. [a]
8. The atmosphere of the group is a friendly one. [b]
Implementation & Preparedness subscale
9. The leaders provide direction for the group. [b]
10. The leaders are prepared for each group session. [b]
11. Group members come prepared for each session. [a]
12. The rules of the group are clearly understood by the members.
13. The activities of the group are carefully planned.
14. The group has an agenda for each meeting.
15. Group activities are easy to follow. [b]
16. Group members are encouraged to act independently.
17. The group concentrates on dealing with everyday problems.
18. Group members learn new ways of solving problems. [b]
19. Group members encourage each other in reaching their goals. [a]
Counterproductive Activity subscale [c]
20. The atmosphere of the group is often hostile. [a]
21. Group members sometimes yell at each other.
22. Group members are engaged in petty quarrels with one another.
23. Sometimes it is hard to tell what is going on in the group.
24. A lot of members just seem to be passing time in group.
25. There seems to be a lot of tension between group members. [b]

[a] newly created item, [b] re-worded item from Moos' original GES, [c] items in the subscale should reverse coded

[1] Wilson, P. A., Hansen, N. B., Tarakeshwar, N., Neufeld, S., Kochman, A., & Sikkema, K. J. (2008). Scale development of a measure to assess community-based and clinical intervention group environments. *Journal of Community Psychology, 36*(3), 271-288.

APPENDIX XXVI: HIV TREATMENT READINESS MEASURE (HTRM)

1. I usually eat at least 3 meals each day.
   1=Strongly Disagree
   2=Disagree
   3=Neither Agree nor Disagree
   4=Agree
   5=Strongly Agree

2. I am ready to start taking HIV medications.
   1=Strongly Disagree
   2=Disagree
   3=Neither Agree nor Disagree
   4=Agree
   5=Strongly Agree

3. Most of the people I live with know my HIV status.
   1=Strongly Disagree
   2=Disagree
   3=Neither Agree nor Disagree
   4=Agree
   5=Strongly Agree

4. I believe taking HIV medications can keep me healthy.
   1=Strongly Disagree
   2=Disagree
   3=Neither Agree nor Disagree
   4=Agree
   5=Strongly Agree

5. In the past 3 months, I found myself wishing I hadn't used street drugs so often.
   1=Strongly Disagree
   2=Disagree
   3=Neither Agree nor Disagree
   4=Agree
   5=Strongly Agree

6. Taking HIV medications would give me bad side effects.
   1=Strongly Disagree
   2=Disagree
   3=Neither Agree nor Disagree
   4=Agree
   5=Strongly Agree

7. I would know how to contact my pharmacist or medical provider if I had problems or questions about HIV medications.
   1=Strongly Disagree
   2=Disagree
   3=Neither Agree nor Disagree
   4=Agree

5=Strongly Agree

8. I feel like I have a stable place to live.
   1=Strongly Disagree
   2=Disagree
   3=Neither Agree nor Disagree
   4=Agree
   5=Strongly Agree

9. If I don't take HIV medications exactly as instructed, the HIV in my body will become resistant to the medications.
   1=Strongly Disagree
   2=Disagree
   3=Neither Agree nor Disagree
   4=Agree
   5=Strongly Agree

10. I have a strong, trusting relationship with my medical provider.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

11. Even though the time may vary on the weekends, I have a regular time when I wake up and go to bed.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

12. I am anxious about my future because I have HIV.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

13. I would know who and when to call for refills for HIV medications.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

14. I sleep in the same bed almost every night.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

15. I can cope with my HIV diagnosis.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

16. Sometimes a homeless shelter is the only place I have to sleep.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

17. Most of my family and friends know my HIV status.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

18. My schedule is different every day.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

19. Taking HIV medication would not really help me.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

20. Even when it may be difficult, I will be able to let my medical provider know if I miss doses of HIV medications.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

21. I regularly go to the clinic and meet with my medical provider.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

22. HIV medications would be poison to my body.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

23. I want to start taking HIV medications.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

24. Despite having HIV, I can move forward with my life.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

25. My household members who know I have HIV would help me remember to take my medication.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

26. Taking HIV medications as prescribed would keep me from getting sick.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

27. I feel supported by my family and friends when times are tough.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

28. I would find it difficult to take pills at the same time every day.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

29. I would take HIV medications even if they made me sick at first because the side effects would go away.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

30. My family and friends who know I have HIV would help me remember to take my medications.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

31. In the past 3 months, I found myself wishing I hadn't drunk alcohol so often.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

32. I know that I will be able to take all of my medication correctly.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

33. I feel confused about what to do about my HIV.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

34. I always eat at least 2 meals each day.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

35. I do not feel respected by my medical provider
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

36. Taking HIV medication would be more trouble than it's worth.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

37. It would be important to me to take HIV medication correctly and on time every day.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

38. In the past 3 months, I have been drunk.
    1=Never
    2=Once
    3=At least once a month
    4=2-3 times per month
    5=At least once a week

39. In the past 3 months, I have used marijuana.
    1=Never
    2=Once
    3=At least once a month
    4=2-3 times per month
    5=At least once a week

40. In the past 3 months, I have used drugs such as crack, meth, or cocaine.
    1=Never
    2=Once
    3=At least once a month
    4=2-3 times per month
    5=At least once a week

In the past month, how often have you.. (Introduction for questions 41 through 47)

41. Felt lonely or sad.
    1=Never
    2=Rarely
    3=Sometimes
    4=Almost Always
    5=Always

42. Been told you seem sad or depressed.
    1=Never
    2=Rarely
    3=Sometimes
    4=Almost Always
    5=Always

43. Felt isolated or lonely, even when around other people.
    1=Never
    2=Rarely
    3=Sometimes
    4=Almost Always
    5=Always

44. Felt that things were going your way.
    1=Never
    2=Rarely
    3=Sometimes
    4=Almost Always
    5=Always

45. Felt confident in your ability to handle your personal problems.
    1=Never
    2=Rarely
    3=Sometimes
    4=Almost Always
    5=Always

46. Felt you could not cope with all the things you had to do.
    1=Never
    2=Rarely
    3=Sometimes
    4=Almost Always
    5=Always

47. In how many different places have you lived in the past year? (Open ended response, ACASI will be programmed to assign 3 or more a value of "1". Otherwise the value will be "5")

48. I shouldn't tell the people I live with that I have HIV.
    1=Strongly Disagree
    2=Disagree
    3=Neither Agree nor Disagree
    4=Agree
    5=Strongly Agree

49. How many people you live with have you told your HIV status?
    1=No one
    2=Only one person
    3=Some people
    4=Most people
    5=Everyone

APPENDIX XXVII: SAMPLE INFORMED CONSENT TEMPLATE

ADOLESCENT TRIALS NETWORK

REMINDER TO STUDY SITES: DO NOT USE THE PREAMBLE IN LOCAL CONSENTS.

NOTE FROM OHRP (OFFICE OF HUMAN RESEARCH PROTECTION) TO SITES ENROLLING PARTICIPANTS IN THIS STUDY:

PLEASE NOTE THAT THIS SAMPLE LANGUAGE DOES NOT PREEMPT OR REPLACE LOCAL IRB REVIEW AND APPROVAL. INVESTIGATORS ARE REQUIRED TO PROVIDE THE LOCAL IRB WITH A COPY OF THIS SAMPLE LANGUAGE ALONG WITH THE LANGUAGE INTENDED FOR LOCAL USE. LOCAL IRBS ARE REQUIRED TO WEIGH THE UNIQUE RISKS, CONSTRAINTS, AND POPULATION CONSIDERATIONS AS A CONDITION OF ANY APPROVAL. ANY DELETION OR SUBSTANTIVE CHANGE OF INFORMATION CONCERNING RISKS OR ALTERNATIVE TREATMENT MUST BE JUSTIFIED BY THE INVESTIGATOR, APPROVED BY THE LOCAL IRB, AND NOTED IN THE IRB MINUTES. JUSTIFICATION AND IRB APPROVAL OF SUCH CHANGES MUST BE FORWARDED TO WESTAT, THE ATN DOC, FOR ANY NICHD-SPONSORED TRIAL, OR AS MAY BE OTHERWISE SPECIFIED. SPONSOR-APPROVED CHANGES IN A PROTOCOL MUST BE APPROVED BY THE LOCAL IRB BEFORE USE UNLESS INTENDED FOR THE ELIMINATION OF APPARENT IMMEDIATE HAZARD. NEW INFORMATION SHALL BE SHARED WITH EXISTING SUBJECTS AT NEXT ENCOUNTER, WITH ALL NEW SUBJECTS PRIOR TO INVOLVEMENT, OR AS THE LOCAL IRB MAY OTHERWISE ADDITIONALLY REQUIRE.

TITLE OF STUDY:

ATN 108 Version 1.0

September 17, 2012

[Protocol title]

Principal Investigator:	[Insert Full Name and Degree(s)]
Address:	[Insert Site Name] [Insert Site Address] [Insert City, State, Zip Code]
Telephone:	[Insert Phone Number]

INTRODUCTION

You are being asked to take part in this research study since you have been diagnosed with HIV, the virus that causes AIDS in the last 15 months, are between the ages 16 and 24 and are willing to participate in individual and group sessions about HIV health care information.

This study is being done to test a program called Project ACCEPT. This program helps HIV-positive youth learn more about HIV and healthy behaviors.

This study will take place in five clinics or health centers across the United States that treat HIV-positive adolescents and young adults. About 240 young people will participate in this study.

PARTICIPATION IN THIS RESEARCH STUDY IS VOLUNTARY

This is a consent form. It gives you information about the study to help you decide if you want to be in the study. It will tell you about the study and what you will be asked to do. It will also tell you the possible risks and benefits, and your rights as a volunteer. You should ask all the questions that you have. When all of your questions are answered, you can decide if you want to be in the study. This process is called "informed consent." Once you understand the study and all your questions are answered, you will be asked to sign this consent form if you want to be in the study. You also will be given a copy of the signed consent form to keep.

DO I HAVE TO JOIN THIS STUDY?

Your participation in this study is completely voluntary. Voluntary means you can decide if you want to be in this study or not. Not joining the study will not change your usual health care or your relationship with any staff at this hospital/program/clinic *(select as applicable)*. You will not lose any benefits if you say no. Also, if you join the study, you can stop being in the study at any time if you so choose. If you stop you will not lose any medical benefits.

WHAT IS THIS STUDY ABOUT?

This study is funded by the Adolescent Trials Network (ATN) and the *Eunice Kennedy Shriver* National Institute for Child Health and Human Development (NICHD).

Often youth, like you, face a number of problems as they move through adolescence and young adulthood. These problems may include having to deal with negative feelings and thoughts about their HIV infection. They also have to learn how to live with a lifelong illness. A program has been developed to help newly diagnosed HIV-positive youth adjust to living with HIV. The purpose of this study is to conduct the program entitled "Adolescents Coping, Connecting, Empowering and Protecting Together" (Project ACCEPT) that was developed to find out how to help youth better adjust to living with HIV. An important part of Project ACCEPT is youth learning to live a healthy life. This can include the importance of accepting your HIV status, connecting with others, empowering yourself to become a healthier person, and protecting yourself by improving your healthy behaviors, including accessing health care services and reducing unhealthy behaviors.

At the same time as testing Project ACCEPT, another program, called HEALTH, will also be tested. HEALTH will give youth information on general health habits, like diet, nutrition and exercise. It will also give information about managing HIV, increasing healthy behaviors, reducing unhealthy behaviors and making future life plans.

Both programs will be tested up to three separate times with different groups of youth each time. After all testing is complete; the results from both programs will be compared to see if Project ACCEPT can help youth live healthier lives.

HOW LONG WILL THE STUDY LAST?

The study is expected to last about three years.

You will be in the study for about one year.

WHAT WILL I HAVE TO DO IN THE STUDY?

If you choose to be in the study, after you sign this consent form, you will be asked to give the staff a list of ways to contact you. Site staff will use your contact information to remind you to come in for your study visits to help set up transportation to your study visit and/or to change your appointment if needed. You will be asked to provide your phone number and an email address. You will also be asked to give contact information for relatives or friends who know how to get in touch with you. You do not have to give any information that you don't want to give. All the contact information you provide will be stored

in a locked cabinet in a locked room. The cabinet is separate from where your study records at the clinical site are stored. Study staff will not leave phone messages unless you give them permission. The staff will not tell your relatives or friends anything about this study, you being in the study, or any other information about you unless you give permission.

Baseline Visit

If you decide to be in this study, first you will sign this consent form. If you meet the conditions for being in the study and it is safe for you to join, then you will have a baseline visit after signing the consent form. At this visit, the following will happen:

- Your medical chart will be reviewed for the following information:
  - Number of medical visits for your HIV care within the last 3 months (about 12 weeks);
  - Any sexually transmitted diseases you may have had within the past 3 months (about 12 weeks);
  - Your most recent viral load;
  - Your most recent CD4 T-cell count and percent; and
  - Any medications you have ever taken for HIV.
- You will complete a confidential questionnaire on a computer that will take about one and a half hours to two hours. Your name or any other information that might link you to your answers will not be asked. Instead, a unique study code assigned to you by the study staff will be used. This means no one will know which answers are yours. This is important because some of the questions ask about your sexual activities and drug use. You do not have to answer any question that you don't want to. However, the study team hopes that you will answer all the questions because they can learn much more if all the questions are answered.

Audio Computer-Assisted Self-Interview (ACASI)

The computer program in which you will answer questions is called an Audio Computer-Assisted Self-Interview or ACASI. ACASI uses a computer and voice recordings so you can hear (through headphones) and see (on the screen) each question and the answer choices for that question. You will enter your answer into the computer. Each ACASI will last approximately one and a half to two hours. When all questions are complete, the computer "locks in" your information. No one at the clinic will see how you answered.

You will be asked general questions like:

- Your age, race, background, gender, school, living situation, pregnancy and parenting status, desire to plan a family;
- Personal questions like how you feel about your health care provider and what types and how often you use health care provider services;
- Other questions including whether you take medication for your HIV, and if so, how well you take your medication;
- Your attitude toward HIV;
- Disclosure of your status;
- HIV stigma;
- Your mood;
- How you feel about condom use;
- What you know about HIV;
- Sexually transmitted diseases you may have had;
- Your experiences with drinking and drug use;
- Your social support;
- Your body weight, diet, and exercise habits;
- If HIV interferes with your life and daily activities; and

- History of risky sexual behaviors.

You do not have to answer any questions that you don't want to answer and you can end the computer interview at any time if you do not want to continue. No one will be able to view any of your answers, not you or the study staff, once you have finished each section of questions. Once you are done answering the ACASI questions, the information will then be encrypted, or put into a secret code. The study staff cannot read the secret code. Then the information is sent to a central location that receives information from all sites doing the study.

Randomization

At the baseline visit you will be randomly assigned to one of the two programs, either Project ACCEPT or HEALTH. Random assignment means that neither you nor the research team has a choice about which intervention you receive. Which group you will be in is decided randomly - like deciding by flipping a coin. Neither you nor your study doctor or nurse gets to choose the group you are in.

Program Visits

Both Project ACCEPT and HEALTH programs have the same number of sessions. You will first have two sessions one-on-one with a trained professional, to talk about your HIV status. If you are in Project ACCEPT, a HIV-positive peer will also be in the session working with the trained professional. The individual sessions will be about one week apart and be about 2 hours each. The sessions will be recorded on a digital recorder so that the researchers do not miss any information given during the sessions and to make sure that the professionals follow the program. The sessions will take place in a private room at (*the ATN site's location)*. At the end of each session you will be asked to complete a questionnaire that will ask you about the sessions, what you liked, did not like, and what you would change.

After completing two individual sessions, you will then have six group sessions with other youth like you who were randomized to the same program. Each group of youth will be separated by gender. That means all the young men in Project ACCEPT will have group sessions together and all the young women in Project ACCEPT will have group sessions together but separate from the young men. The same is true for HEALTH. All young men in HEALTH will have group sessions by themselves and all young women in HEALTH will be in their own group sessions.

The group sessions will be about one week apart from each other for about six weeks. Each session will be about two hours long. The same trained professional that you meet with during your individual sessions will lead the group sessions. If you are in Project ACCEPT, a HIV-positive peer will also be in the sessions working with the trained professional.

In group sessions you will be asked to share your experiences and what you think might have been helpful to you in learning to live with your HIV infection. The group sessions will be recorded on a digital recorder so that the researchers do not miss any information given during the sessions and to ensure that the professionals follow the program. The group sessions will take place in a private room at (*the ATN site's location)*. At the end of each group session you will be asked to complete a questionnaire, the same as after the individual sessions.

After the six group sessions, you will have a final individual session, like the first two sessions that took place before the group sessions. This session will also be recorded on digital recorder and be about two hours long. The same as after other sessions, you will be asked to complete a questionnaire about the session.

Follow-up Visits after the Program Visit (Immediately, 3, 6, and 12 months after last individual session)

After all individual and group sessions are completed, you will have four follow-up visits. The follow-up visits take place immediately after the last session, then 3, 6 and 12 months after the last session. At these visits, the following will happen just as done at the baseline visit:

- Your medical chart will be reviewed for the following:
  - Number of medical visits for your HIV care within the last 3 months (about 12 weeks);
  - Any sexually transmitted diseases you may have had within the past 3 months (about 12 weeks);
  - Your most recent viral load;
  - Your most recent CD4 T-cell count and percent; and
  - Any medications you have taken for HIV.
- You will complete an ACASI on a computer just as you did at the baseline visit.

At the follow-up visit immediately after the last session, the ACASI will have extra questions that will ask about what you learned and if you liked the program and group leaders.

Premature Discontinuation from the Program

The following are reasons you may have to stop taking part in the group sessions:

- You disrupt the group sessions repeatedly. This means you cause harm to other youth in the group by:
  - Not participating or responding to questions;
  - Missing too many of the sessions;
  - Showing up to sessions high or drunk; or
  - Being rude or disrespectful of other youth in the group.

If you are asked to stop taking part in the group sessions, you still will be able to continue being in the study by completing the four follow-up visits at immediately, 3, 6, and 12 months after the last session.

Premature Study Discontinuation

If, for any reason, you want to stop being in the study completely, you can stop at any time. However, any study information that has already been collected about you will continue to be part of the study results. The information will be used for analysis.

WHAT ARE SOME POSSIBLE RISKS?

Taking part in this study does not involve any physical risk to you. However, some of the questions or topics you will be discussing may be embarrassing, may make you uncomfortable, or may be upsetting because they involve sensitive topics and behaviors. If you become very upset or issues come up that you want to discuss privately, there are counselors at (*insert ATN site's location*) for you to talk to. You do not have to answer any questions in the questionnaires or sessions you do not want to answer. At any point, you may stop if you do not wish to continue answering the questions. You will not lose any benefits that you may have received prior to study participation.

All participants in the study are HIV-positive. By participating in the group sessions, you are letting those in the group know that you are also HIV-positive. Prior to each session participants will be reminded of the following rules that will need to be followed:

- To treat each other with respect and not say anything to another participant that may insult or harm him/her in any way;
- Not to discuss what is stated during the group sessions with others outside the group. However, there is no guarantee that everyone will keep the information confidential (private); and
- Not to use any of the other participants' names if you happen to know them.

This list of risks and discomforts may be incomplete, and does not include risks and discomforts that we do not yet know about. You will be informed if the study staff learn of any new risks.

WHAT ARE THE BENEFITS TO ME?

There is no guarantee that you will receive any direct benefit from being in the study. However, you may benefit from the support from others in the group and the new information you learn during the sessions. The different sessions may help you to better understand your own health needs, risk behaviors, or potential risk behaviors. The sessions may help you learn ways to improve your own health and reduce or avoid your personal risk behaviors; however, we cannot guarantee that this will happen.

The information learned from this study will be used to improve activities and interviews that are part of the programs so that they can be used to help other youth living with HIV in the future.

ARE THERE ANY COSTS TO ME FOR TAKING PART IN THIS STUDY?

You will not be charged for anything we do that is part of this study. You will not receive any medications or medical treatments as part of this study. You or your health insurance company will have to pay for any medical care that is not part of this study, as you would usually do.

WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS STUDY (WHAT OTHER CHOICES DO I HAVE)?

You may choose not to join this study. If you do join, you can stop at any time. Whatever you decide, it will not change your regular health care benefits. It will also not change your ability to be in other studies in the future. You will still get services from *(insert ATN site's location).* There may be other studies going on here or in the hospital that you may be eligible for. The study staff can tell you about these other studies. You can also talk to the study doctor or nurse about other choices that may be available to you.

WILL I BE TOLD IF THERE ARE NEW FINDINGS?

You will be told of any new information learned during the course of the study that might cause you to change your mind about being in the study. At the end of the study, you will be told when study results may be available and how to learn about them.

ARE THERE ANY REASONS WHY I MAY BE ASKED TO STOP TAKING PART IN THE STUDY?

You may choose to stop taking part in this study at any time (withdraw your consent). The following are other reasons you may have to stop taking part in the study:

- You do not complete the first two individual sessions before the start of the group sessions;
- You are unable to follow the study requirements, like coming in for study visits, or disclosing private information to others that was shared within the group sessions;
- Your doctor decides that the study is harmful to you;
- You need a treatment that would interfere with the results of the study;
- You become incarcerated or detained;
- Your parent or legal guardian gave permission for you to be in the study and your parent or legal guardian changes his/her mind;
- The study is stopped by the National Institutes of Health (NIH), the government agency sponsoring this study;
- The study is stopped by the Institutional Review Board (IRB) at *(name of institution)* (an IRB is a committee that watches over the safety and rights of research participants); or
- The study has to be stopped for other administrative reasons.

WHAT WILL I GET FOR TAKING PART IN THIS STUDY?

You (will/will not) be given *($X*)/money) for your time (at each study visit). Food/A food voucher worth $X (will/will not) be provided (at each study visit). Transportation costs (will/will not) be paid. *(Insert site-specific details of compensation.)*

WILL MY TAKING PART IN THE STUDY BE KEPT PRIVATE?

Your participation in this study will be kept confidential (private) as permitted by law. This includes the information you provide on the questionnaires and your lab test results. All your responses to the computerized questionnaire will be kept confidential. The study doctors and nurses at your site will NOT be able see your answers to the questions. You will be assigned a unique code number that will be used on the questionnaires and all study forms. The list that links your name with your unique code number will be kept in a locked cabinet in a locked room at the clinical site. Staff members involved in conducting this study are required to sign a form stating that they will protect information of all youth in the study.

Your information from the study will be coded and stored at Westat, the ATN Data and Operations Center (DOC) in Rockville, MD. The ATN DOC will provide the study researchers with limited coded information for analysis. All answers will be grouped together. Answers will not be linked to any one individual. If reports or results are shared with the study team and the research staff at this site, no one will know what information is yours. Information about the study may be published in a scientific magazine or presented at a scientific meeting or used by other researchers, but names or other personal information will never be used.

Research staff at John H. Stroger, Jr. Hospital of Cook County, IL will receive the digital recordings of the individual and group sessions. The recordings will be digital files, and will be stored on a secure computer at the clinic and then sent to John H. Stroger, Jr. Hospital of Cook County through a secure server at the ATN DOC. The files will not identify you. At the end of the study the files will be permanently deleted.

Every effort will be made to keep your being in the study and your personal information private and confidential; but, absolute confidentiality cannot be guaranteed. For example, if a staff member learns something that would immediately put you or others in danger, the staff member is required by law to take steps to keep you and others safe. This means that staff members have to report to the authorities (hospital, police, or social services) any information you say that suggests that you might be in danger, like if you say you plan to hurt or kill yourself, hurt or kill someone else, or if someone is abusing or neglecting you.

In addition, your records may be reviewed. Under the guidelines of the Federal Privacy Act, the sponsoring agency at the NIH, the study monitors at the ATN DOC acting on behalf of NIH, and (*Name of IRB*) may look at your records to make sure that the study staff is doing what they are supposed to and that youth in the study are protected. If your study records are reviewed, your identity could become known to them. However, these persons are expected to maintain your individual confidentiality, meaning that they will not tell others information about you or about your being in the study.

Finally, because the study involves taking part in a group session, your HIV status will be known by the other HIV-positive youth in the group. Everyone will be reminded at the beginning of each group session to treat each group member with respect, to not say anything to another youth that may insult or harm him/her in any way, to not to discuss what is stated during the group sessions with others outside the group, and to not to use any of the other participants' names if you happen to know them. However, we cannot promise that everyone will keep the information confidential (private).

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CERTIFICATE OF CONFIDENTIALITY

To help further protect your privacy, the ATN has obtained a Confidentiality Certificate from the U.S. Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example by court subpoena) to give research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. But, as mentioned above, your records may be reviewed by NIH to make sure that the study is being done the way it is supposed to.

You should understand that a Confidentiality Certificate does not prevent you from releasing information about your involvement in this research if you want to. This means that if someone (like an insurer or employer) finds out about your research specimens or research information, asks you for it and you say it is okay for them to have it, then the researcher here cannot use the Certificate to keep your information private. Your research information would have to be turned over. This means that you must also actively protect your own privacy. You have to be careful about who you permit to look at your research information.

WHAT HAPPENS IF I AM INJURED? (POLICY REGARDING RESEARCH-RELATED INJURY)

If you are injured as a result of being in this research study, you will receive immediate, short-term treatment as determined by (*name of hospital*) for the injury. The cost of the treatment will be charged to you or your insurance company, as would normally be done for your medical care. You will then be told where you could receive additional treatment for injuries. Your insurance carrier may or may not pay for treatments for injuries that are caused by taking part in this study. No monetary compensation (payment to you) or other forms of compensation for such injuries will be provided by the hospital or sponsoring agency.

WHAT IF I WANT TO STOP TAKING PART IN THIS STUDY?

Taking part in this study is completely voluntary. You may choose not to take part in this study. You may leave this study at any time. You will be treated the same no matter what you decide. Information collected from you prior to your deciding to stop taking part in the study may be used in the study analysis.

WHO DO I CONTACT IF I HAVE PROBLEMS OR QUESTIONS ABOUT THE STUDY?

The doctor in charge of this study at (*name of hospital*) is Dr. (*name of PI*). The study nurse is (*name of study coordinator*). You may call them at (*telephone number*) if you ever have questions about this study or in case of research-related injuries. In addition, if you have any questions about your rights as a research participant, you may call (*IRB contact person name and title*) at the (*name of hospital's*) Institutional Review Board at (*telephone number*).

STATEMENT OF CONSENT

The purpose of this research study, what you will be asked to do, and the risks and benefits of the study have been explained to you. You have been given the time to ask any questions you might have about this study. You have been told that participation in this study is voluntary. You may be in the study only if you wish. You may refuse to stop being in the study at any time without affecting your future treatment at this hospital/clinic or your future relations with the hospital or its employees.

(NOTE: This is only a suggested signature format. Sites may use their own signature page.)

By signing this consent document, you are agreeing to take part in the study described to you. You will be given a copy of this signed consent form to keep.

Participant's Name (print)	Participant's Signature	Date

PI or Designee's statement:

I have reviewed this study and the consent form with the participant. To the best of my knowledge, he/she understands the purpose, procedures, risks, and benefits of the study.

PI or Designee's Name (print)	PI or Designee's Signature	Date

NOTE: This consent form with the original signatures MUST be retained on file by the principal investigator. A copy must be given to the participant. A copy should be placed in the participant's medical record, if applicable.

APPENDIX XXVIII: SAMPLE PARENTAL PERMISSION TEMPLATE

ADOLESCENT TRIALS NETWORK

REMINDER TO STUDY SITES: DO NOT USE THE PREAMBLE IN LOCAL CONSENTS.

NOTE FROM OHRP (OFFICE OF HUMAN RESEARCH PROTECTION) TO SITES ENROLLING PARTICIPANTS IN THIS STUDY:

PLEASE NOTE THAT THIS SAMPLE LANGUAGE DOES NOT PREEMPT OR REPLACE LOCAL IRB REVIEW AND APPROVAL. INVESTIGATORS ARE REQUIRED TO PROVIDE THE LOCAL IRB WITH A COPY OF THIS SAMPLE LANGUAGE ALONG WITH THE LANGUAGE INTENDED FOR LOCAL USE. LOCAL IRBS ARE REQUIRED TO WEIGH THE UNIQUE RISKS, CONSTRAINTS, AND POPULATION CONSIDERATIONS AS A CONDITION OF ANY APPROVAL. ANY DELETION OR SUBSTANTIVE CHANGE OF INFORMATION CONCERNING RISKS OR ALTERNATIVE TREATMENT MUST BE JUSTIFIED BY THE INVESTIGATOR, APPROVED BY THE LOCAL IRB, AND NOTED IN THE IRB MINUTES. JUSTIFICATION AND IRB APPROVAL OF SUCH CHANGES MUST BE FORWARDED TO WESTAT, THE ATN DOC, FOR ANY NICHD-SPONSORED TRIAL, OR AS MAY BE OTHERWISE SPECIFIED. SPONSOR-APPROVED CHANGES IN A PROTOCOL MUST BE APPROVED BY THE LOCAL IRB BEFORE USE UNLESS INTENDED FOR THE ELIMINATION OF APPARENT IMMEDIATE HAZARD. NEW INFORMATION SHALL BE SHARED WITH EXISTING SUBJECTS AT NEXT ENCOUNTER, WITH ALL NEW SUBJECTS PRIOR TO INVOLVEMENT, OR AS THE LOCAL IRB MAY OTHERWISE ADDITIONALLY REQUIRE.

TITLE OF STUDY:

ATN 108 Version 1.0

September 17, 2012

[Protocol title]

Principal Investigator:	[Insert Full Name and Degree(s)]
Address:	[Insert Site Name] [Insert Site Address] [Insert City, State, Zip Code]
Telephone:	[Insert Phone Number]

INTRODUCTION

You are being asked to allow your youth to take part in this research study since he/she has been diagnosed with HIV, the virus that causes AIDS in the last 15 months, is between the ages 16 and 24 and willing to participate in individual and group sessions about HIV health care information.

This study is being done to test a program called Project ACCEPT. This program helps HIV-positive youth learn more about HIV and healthy behaviors.

This study will take place in five clinics or health centers across the United States that treat HIV-positive adolescents and young adults. About 240 young people will participate in this study.

PARTICIPATION IN THIS RESEARCH STUDY IS VOLUNTARY

This is a consent form. It gives you information about the study to help you decide if you want to allow your youth to be in the study. It will tell you about the study and what your youth will be asked to do. It will also tell you the possible risks and benefits, and your youth's rights as a volunteer. You should ask all the questions that you have. When all of your questions are answered, you can decide if you want to allow your youth to be in the study. This process is called "informed consent." Once you understand the study and all your questions are answered, you will be asked to sign this consent form if you want to allow your youth to be in the study. You also will be given a copy of the signed consent form to keep.

DOES MY YOUTH HAVE TO JOIN THIS STUDY?

Your permission to allow your youth to participate in this study is completely voluntary. Voluntary means you can decide if you want to allow your youth to be in this study or not. Not joining the study will not change your youth's usual health care or his/her relationship with any staff at this hospital/program/clinic *(select as applicable)*. Your youth will not lose any benefits if you say no. Also, if you allow your youth to join the study, you can stop her/him from being in the study at any time if you so choose. If your youth stops the study, he/she will not lose any medical benefits.

WHAT IS THIS STUDY ABOUT?

This study is funded by the Adolescent Trials Network (ATN) and the *Eunice Kennedy Shriver* National Institute for Child Health and Human Development (NICHD).

Often, youth face a number of problems as they move through adolescence and young adulthood. These problems may include having to deal with negative feelings and thoughts about their HIV infection. They also have to learn how to live with a lifelong illness. A program has been developed to help newly diagnosed HIV-positive youth adjust to living with HIV. The purpose of this study is to conduct the program entitled "Adolescents Coping, Connecting, Empowering and Protecting Together" (Project ACCEPT) that was developed to find out how to help youth better adjust to living with HIV. An important part of Project ACCEPT is youth learning to live a healthy life. This can include the importance of accepting their HIV status, connecting with others, empowering oneself to become a healthier person, and protecting oneself by improving healthy behaviors, including accessing health care services and reducing unhealthy behaviors.

At the same time as testing Project ACCEPT, another program, called HEALTH, will also be tested. HEALTH will give youth information on general health habits, like diet, nutrition and exercise. It will also give information about managing HIV, increasing healthy behaviors, reducing unhealthy behaviors and making future life plans.

Both programs will be tested up to three separate times with different groups of youth each time. After all testing is complete, the results from both programs will be compared to see if Project ACCEPT can help youth live healthier lives.

HOW LONG WILL THE STUDY LAST?

The study is expected to last about three years.

Your youth will be in the study for about one year.

WHAT WILL MY YOUTH HAVE TO DO IN THE STUDY?

If you choose to allow your youth to be in the study, after you sign this consent form, your youth will be asked to give the staff a list of ways to contact him/her. Site staff will use your youth's contact information to remind him/her to come in for study visits to help set up transportation to study visits and/or to change his/her appointments if needed. Your youth will be asked to provide a phone number and an email address. He/she will also be asked to give contact information for relatives or friends who know

how to get in touch with him/her. Your youth does not have to give any information that he/she doesn't want to give. All the contact information he/she provides will be stored in a locked cabinet in a locked room. The cabinet is separate from where your youth's study records at the clinical site are stored. Study staff will not leave phone messages unless your youth gives them permission. The staff will not tell your youth's relatives or friends anything about this study, him/her being in the study, or any other information about him/her unless your youth gives permission.

Baseline Visit

If your youth meets the conditions for being in the study and it is safe for him/her to join, then he/she will have a baseline visit after signing the consent form. At this visit, the following will happen:

- Your youth's medical chart will be reviewed for the following information:
  - Number of medical visits for HIV care within the last 3 months (about 12 weeks);
  - Any sexually transmitted diseases he/she may have had within the past 3 months (about 12 weeks);
  - Most recent viral load;
  - Most recent CD4 T-cell count and percent; and
  - Any medications he/she has ever taken for HIV.
- Your youth will complete a confidential questionnaire on a computer that will take about one and a half hours to two hours. His/her name or any other information that might link him/her to his/her answers will not be asked. Instead, a unique study code assigned to your youth by the study staff will be used. This means no one will know which answers are your youth's. This is important because some of the questions ask about sexual activities and drug use. Your youth does not have to answer any questions that he/she doesn't want to. However, the study team hopes that he/she will answer all the questions because they can learn much more if all the questions are answered.

Audio Computer-Assisted Self-Interview (ACASI)

The computer program in which your youth will answer questions is called an Audio Computer-Assisted Self-Interview or ACASI. ACASI uses a computer and voice recordings so your youth can hear (through headphones) and see (on the screen) each question and the answer choices for that question. Your youth will enter his/her answers into the computer. Each ACASI will last approximately one and a half to two hours. When all questions are complete, the computer "locks in" your youth's information. No one at the clinic will see how your youth answered.

Your youth will be asked general questions like:

- His/her age, race, background, gender, school, living situation, pregnancy and parenting status, desire to plan a family;
- Personal questions like how he/she feels about his/her health care provider and what types and how often he/she uses health care provider services;
- Other questions including whether he/she takes medication for HIV, and if so, how well he/she takes the medication;
- His/her attitude toward HIV;
- Disclosure of HIV status;
- HIV stigma;
- Mood;
- How he/she feels about condom use;
- What he/she knows about HIV;
- Sexually transmitted diseases he/she may have had;
- His/her experiences with drinking and drug use;
- Social support;

- Body weight, diet, and exercise habits;
- If HIV interferes with his/her life and daily activities; and
- History of risky sexual behaviors.

Your youth does not have to answer any questions that he/she doesn't want to answer and he/she can end the computer interview at any time if he/she does not want to continue. No one will be able to view any of your youth's answers, not you, your youth or the study staff, once he/she has finished each section of questions. Once your youth is done answering the ACASI questions, the information will then be encrypted, or put into a secret code. The study staff cannot read the secret code. Then the information is sent to a central location that receives information from all sites doing the study.

Randomization

At the baseline visit your youth will be randomly assigned to one of the two programs, either Project ACCEPT or HEALTH. Random assignment means that neither your youth nor the research team has a choice about which intervention your youth receives. Which group he/she will be in is decided randomly – like deciding by flipping a coin. Neither you, your youth or the study doctor or nurse gets to choose the group your youth is in.

Program Visits

Both Project ACCEPT and HEALTH programs have the same number of sessions. Your youth will first have two sessions one-on-one with a trained professional, to talk about his/her HIV status. If you are in Project ACCEPT, a HIV-positive peer will also be in the session working with the trained professional. The individual sessions will be about one week apart and be about 2 hours each. The sessions will be recorded on a digital recorder so that the researchers do not miss any information given during the sessions and to make sure that the professionals follow the program. The sessions will take place in a private room at (*the ATN site's location).* At the end of each session your youth will be asked to complete a questionnaire that will ask about the sessions, what he/she liked, did not like, and what he/she would change.

After completing two individual sessions, your youth will then have six group sessions with other youth who were randomized to the same program. Each group of youth will be separated by gender. That means all the young men in Project ACCEPT will have group sessions together and all the young women in Project ACCEPT will have group sessions together but separate from the young men. The same is true for HEALTH. All young men in HEALTH will have group sessions by themselves and all young women in HEALTH will be in their own group sessions.

The group sessions will be about one week apart from each other for about six weeks. Each group session will be about two hours long. The same trained professional that your youth met with during individual sessions will lead the group sessions. If your youth is in Project ACCEPT, a HIV-positive peer will also be in the sessions with the trained professional.

In group sessions your youth will be asked to share experiences and what he/she thinks might have been helpful to learning to live with HIV infection. The group sessions will be recorded on a digital recorder so that the researchers do not miss any information given during the sessions and to ensure that the professionals follow the program. The group sessions will take place in a private room at (*the ATN site's location).* At the end of each group session your youth will be asked to complete a questionnaire, the same as after the individual sessions.

After the six group sessions, your youth will have a final individual session, like the first two sessions that took place before the group sessions. This session will also be recorded on digital recorder and be about

two hours long. The same as after other sessions, your youth will be asked to complete a questionnaire about the session.

Follow-up Visits after the Program Visit (Immediately, 3, 6, and 12 months after last individual session)
After all individual and group sessions are completed, your youth will have four follow-up visits. The follow-up visits take place immediately after the last session, then 3, 6 and 12 months after the last session. At these visits, the following will happen just as done at the baseline visit:

- Your youth's medical chart will be reviewed for the following:
  - Number of medical visits for HIV care within the last 3 months (about 12 weeks);
  - Any sexually transmitted diseases within the past 3 months (about 12 weeks);
  - Most recent viral load;
  - Most recent CD4 T-cell count and percent; and
  - Any medications taken for HIV.
- Your youth will also complete an ACASI on a computer just as was done at the baseline visit.

At the follow-up visit immediately after the last session, the ACASI will have extra questions that will ask about what your youth learned and if he/she liked the program and group leaders.

Premature Discontinuation from the Program
The following are reasons your youth may have to stop taking part in the group sessions:

- He/she disrupts the group sessions repeatedly. This means he/she caused harm to other youth in the group by:
  - Not participating or responding to questions;
  - Missing too many of the sessions;
  - Showing up to sessions high or drunk; or
  - Being rude or disrespectful of other youth in the group.

If your youth is asked to stop taking part in the group sessions, he/she will be able to continue being in the study and will complete the four follow-up visits at immediately, 3, 6, and 12 months after the last session.

Premature Study Discontinuation
If, for any reason, you want your youth or your youth wants to stop being in the study completely, he/she can stop at any time. However, any study information that has already been collected about him/her will continue to be part of the study results. The information will be used for analysis.

WHAT ARE SOME POSSIBLE RISKS?
Taking part in this study does not involve any physical risk to your youth. However, some of the questions or topics that will be discussed may be embarrassing, may make your youth uncomfortable, or may be upsetting because they involve sensitive topics and behaviors. If your youth becomes very upset or issues come up that he/she wants to discuss privately, there are counselors at (*insert ATN site's location*) for him/her to talk to. Your youth does not have to answer any questions in the questionnaires or sessions that he/she does not want to answer. At any point, your youth may stop if he/she does not wish to continue answering the questions. Your youth will not lose any benefits that he/she may have received prior to study participation.

All participants in the study are HIV-positive. By participating in the group sessions, your youth is letting those in the group know that he/she is also HIV-positive. Prior to each session participants will be reminded of the following rules that will need to be followed:

- To treat each other with respect and not say anything to another participant that may insult or harm him/her in any way;
- Not to discuss what is stated during the group sessions with others outside the group. However, there is no guarantee that everyone will keep the information confidential (private); and
- Not to use any of the other participants' names if youth happen to know each other.

This list of risks and discomforts may be incomplete and does not include risks and discomforts that we do not know about yet. Your youth will be informed if the study staff learn of any new risks.

WHAT ARE THE BENEFITS TO MY YOUTH?

There is no guarantee that your youth will receive any direct benefit from being in the study. However, he/she may benefit from the support from others in the group and the new information learned during the sessions. The different sessions may help your youth to better understand his/her own health needs, risk behaviors, or potential risk behaviors. The sessions may help him/her learn ways to improve his/her own health and reduce or avoid personal risk behaviors; however, we cannot guarantee that this will happen.

The information learned from this study will be used to improve activities and interviews that are part of the programs so that they can be used to help other youth living with HIV in the future.

ARE THERE ANY COSTS TO ME OR MY YOUTH FOR TAKING PART IN THIS STUDY?

Your youth will not be charged for anything we do that is part of this study. He/she will not receive any medications or medical treatments as part of this study. You or your youth's health insurance company will have to pay for any medical care that is not part of this study, as you would usually do.

WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS STUDY (WHAT OTHER CHOICES DOES MY YOUTH HAVE)?

You may choose not to allow your youth to join this study. If you do choose to let him/her join, you can stop him/her being in the study at any time. Whatever you decide, it will not change your youth's regular health care benefits. It will also not change your youth's ability to be in other studies in the future. Your youth will still get services from *(insert ATN site's location).* There may be other studies going on here or in the hospital that your youth may be eligible for. The study staff can tell you about these other studies. You can also talk to the study doctor or nurse about other choices that may be available to your youth.

WILL I BE TOLD IF THERE ARE NEW FINDINGS?

Your and your youth will be told of any new information learned during the course of the study that might cause you or your youth to change your mind about being in the study. At the end of the study, your youth will be told when study results may be available and how to learn about them.

ARE THERE ANY REASONS WHY MY YOUTH MAY BE ASKED TO STOP TAKING PART IN THE STUDY?

Your youth may choose to stop taking part in this study at any time (withdraw consent). The following are other reasons your youth may have to stop taking part in the study:

- He/she does not complete the first two individual sessions before the start of the group sessions;
- He/she is unable to follow the study requirements, like coming in for study visits, or disclosing private information to others that was shared within the group sessions;
- His/her doctor decides that the study is harmful to him/her;
- He/she needs a treatment that would interfere with the results of the study;
- He/she becomes incarcerated or detained;
- You change your mind and want your youth to stop being in the study;

- The study is stopped by the National Institutes of Health (NIH), the government agency sponsoring this study;
- The study is stopped by the Institutional Review Board (IRB) at *(name of institution)* (an IRB is a committee that watches over the safety and rights of research participants); or
- The study has to be stopped for other administrative reasons.

WHAT WILL MY YOUTH GET FOR TAKING PART IN THIS STUDY?

Your youth (will/will not) be given *($X*)/money) for his/her time (at each study visit). Food/A food voucher worth $X (will/will not) be provided (at each study visit). Transportation costs (will/will not) be paid. *(Insert site-specific details of compensation.)*

WILL MY YOUTH'S TAKING PART IN THE STUDY BE KEPT PRIVATE?

Your youth's participation in this study will be kept confidential (private) as permitted by law. This includes the information he/she provides on the questionnaires and lab test results. All your youth's responses to the computerized questionnaire will be kept confidential. The study doctors and nurses at the site will NOT be able see his/her answers to the questions. Your youth will be assigned a unique code number that will be used on the questionnaires and all study forms. The list that links your youth's name with his/her unique code number will be kept in a locked cabinet in a locked room at the clinical site. Staff members involved in conducting this study are required to sign a form stating that they will protect information of all youth in the study.

Your youth's information from the study will be coded and stored at Westat, the ATN Data and Operations Center (DOC) in Rockville, MD. The ATN DOC will provide the study researchers with limited coded information for analysis. All answers will be grouped together. Answers will not be linked to any one individual. If reports or results are shared with the study team and the research staff at this site, no one will know what information is your youth's. Information about the study may be published in a scientific magazine or presented at a scientific meeting or used by other researchers, but names or other personal information will never be used.

Research staff at John H. Stroger, Jr. Hospital of Cook County, IL will receive the digital recordings of the individual and group sessions. The recordings will be digital files, and will be stored on a secure computer at the clinic and then sent to John H. Stroger, Jr. Hospital of Cook County through a secure server at the ATN DOC. The files will not identify your youth. At the end of the study the files will be permanently deleted.

Every effort will be made to keep your youth being in the study and his/her personal information private and confidential, but absolute confidentiality cannot be guaranteed. For example, if a staff member learns something that would immediately put your youth or others in danger, the staff member is required by law to take steps to keep him/her and others safe. This means that staff members have to report to the authorities (hospital, police, or social services) any information your youth says that suggests that he/she might be in danger, like if your youth says he/she plans to hurt or kill him/herself, hurt or kill someone else, or if someone is abusing or neglecting your youth.

In addition, your youth's records may be reviewed. Under the guidelines of the Federal Privacy Act, the sponsoring agency at the NIH, the study monitors at the ATN DOC acting on behalf of NIH, and (*Name of IRB*) may look at your youth's records to make sure that the study staff is doing what they are supposed to and that youth in the study are protected. If your youth's study records are reviewed, his/her identity could become known to them. However, these persons are expected to maintain your youth's individual confidentiality, meaning that they will not tell others information about your youth or about him/her being in the study.

Finally, because the study involves taking part in a group session, your youth's HIV status will be known by the other HIV-positive youth in the group. Everyone will be reminded at the beginning of each group session to treat each group member with respect, to not say anything to another youth that may insult or harm him/her in any way, to not to discuss what is stated during the group sessions with others outside the group, and to not use any of the other participants' names if your youth happen to know them. However, we cannot promise that everyone will keep the information confidential (private).

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify your youth. At most, the Web site will include a summary of the results. You or your youth can search this Web site at any time.

CERTIFICATE OF CONFIDENTIALITY

To help further protect your youth's privacy, the ATN has obtained a Confidentiality Certificate from the U.S. Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example by court subpoena) to give research information that may identify your youth in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. But, as mentioned above, your youth's records may be reviewed by NIH to make sure that the study is being done the way it is supposed to.

You and your youth should understand that a Confidentiality Certificate does not prevent your youth from releasing information about his/her involvement in this research if he/she wants to. This means that if someone (like an insurer or employer) finds out about your youth's research specimens or research information, asks your youth for it and he/she says it is okay for them to have it, then the researcher here cannot use the Certificate to keep the information private. Your youth's research information would have to be turned over. This means that your youth must also actively protect his/her own privacy. Your youth has to be careful about who he/she permits to look at his/her research information.

WHAT HAPPENS IF MY YOUTH IS INJURED? (POLICY REGARDING RESEARCH-RELATED INJURY)

If your youth is injured as a result of being in this research study, he/she will receive immediate, short-term treatment as determined by (*name of hospital*) for the injury. The cost of the treatment will be charged to you or your youth's insurance company, as would normally be done for his/her medical care. Your youth will then be told where he/she can receive additional treatment for injuries. Your youth's insurance carrier may or may not pay for treatments for injuries that are caused by taking part in this study. No monetary compensation (payment to you or your youth) or other forms of compensation for such injuries will be provided by the hospital or sponsoring agency.

WHAT IF I WANT MY YOUTH TO STOP TAKING PART IN THIS STUDY?

Taking part in this study is completely voluntary. You may choose not to allow your youth to take part in this study. Your youth may leave this study at any time. He/she will be treated the same no matter what you decide. Information collected from your youth prior to his/her deciding to stop taking part in the study may be used in the study analysis.

WHO DO I CONTACT IF I HAVE PROBLEMS OR QUESTIONS ABOUT THE STUDY?

The doctor in charge of this study at (*name of hospital*) is Dr. (*name of PI*). The study nurse is (*name of study coordinator*). You may call them at (*telephone number*) if you ever have questions about this study or in case of research-related injuries. In addition, if you have any questions about your youth's rights as a research participant, you may call (*IRB contact person name and title*) at the (*name of hospital's*) Institutional Review Board at (*telephone number*).

STATEMENT OF CONSENT

The purpose of this research study, what you will be asked to do, and the risks and benefits of the study have been explained to you. You have been given the time to ask any questions you might have about this study. You have been told that participation in this study is voluntary. You may allow your youth to be in the study only if you wish. You may refuse or stop your youth being in the study at any time without affecting his/her future treatment at this hospital/clinic or his/her future relations with the hospital or its employees.

(NOTE: This is only a suggested signature format. Sites may use their own signature page.)

By signing this consent document, you are agreeing to take part in the study described to you. You will be given a copy of this signed consent form to keep.

Parent or Legal Guardian's Name (print)	Parent or Legal Guardian's Signature	Date

PI or Designee's statement:

I have reviewed this study and the consent form with the participant. To the best of my knowledge, he/she understands the purpose, procedures, risks, and benefits of the study.

PI or Designee's Name (print)	PI or Designee's Signature	Date

NOTE: This consent form with the original signatures MUST be retained on file by the principal investigator. A copy must be given to the participant. A copy should be placed in the participant's medical record, if applicable.