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Work2Prevent: Employment as HIV prevention for young men who have sex with men (YMSM) and young transgender women (YTW)

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

Sponsored by:
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TABLE OF CONTENTS

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STUDY MANAGEMENT

Before the recruitment and enrollment of participants, the participating study site must have the protocol and consent form approved by their local Institutional Review Boards (IRBs). In addition, study site must receive protocol registration approval from the ATN Coordinating Center (CC) by submitting a complete registration packet with the site's IRB approved documents and a site registration form. All original approved documents must be maintained at the clinical site.

All queries for this protocol should be sent to the ATN *(151)* project team using the ATN Protocol Query and Notification System (QNS) accessible via the ATN website (https://sites.cscc.unc.edu/atn/). The appropriate team member will respond to queries generally within 48 business hours via the ATN QNS. The Protocol Manager, with the help of other ATN CC personnel, Protocol Chair and/or NICHD, if necessary, will answer queries related to general protocol implementation, eligibility and CRF completion. The Protocol Chair or his/her designee will respond to study and participant management, exemptions and/or untoward event queries. This study follows the ATN Policy for Guidance for Safety and Impact Reporting. Queries and replies will automatically be archived at the ATN CC. The CC will post those queries deemed relevant to all sites on the ATN 151 FAQ page, where they will be available for future reference.

This study will use the Audio Computer-Assisted Self-Interview (ACASI) to collect study data. All questions related to the ACASI should be directed to the ATN Help Desk at the ATN CC by calling the toll-free ATN ACASI helpline at 1 (866) 257-7242 or by email (ATNhelp@unc.edu).

For protocol registration issues, contact the ATN Coordinating Center ATNhelp@unc.edu.

LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

ACASI	Audio Computer Assisted Self Interview
AEs	Adverse Events
AFC	AIDS Foundation Chicago
AIDS	Acquired Immunodeficiency Syndrome
ATN	Adolescent Medicine Trials Network for HIV/AIDS Interventions
CAB	Community Advisory Board
CDART	Carolina Data Acquisition and Reporting Tool
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CGSHP	Lurie Children's Hospital Center for Gender, Sexuality and HIV Prevention
Ci3	Center for Interdisciplinary Inquiry & Innovation in Sexual and Reproductive Health
CRF	Case Report Form
CT	Chlamydia
DHHS	U.S. Department of Health and Human Services
CC	ATN Coordinating Center
eCRF	Electronic Case Report Form
GC	Gonorrhea
GEE	Generalized Estimating Equations
HBM	Health Belief Model
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Virus
HRSA	Heath Resources and Services Administration
IATA	International Air Transport Association
ICH	International Conference on Harmonization
iFOUR	Increase Individual Income and Independence Program
IRB	Institutional Review Board
LGBT	Lesbian Gay Bisexual Transgender
MATEC	Midwest AIDS Training and Education
MSM	Man who has sex with men
NICHD	National Institute of Child Health and Development
NIDA	National Institute on Drug Abuse
NIH	National Institutes of Health

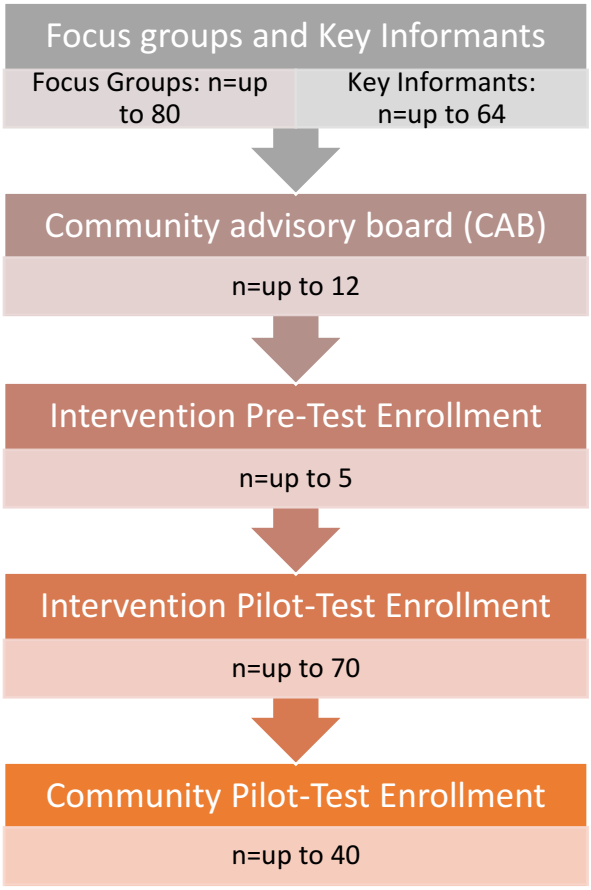
OHRP	Office of Human Research Protection
OSHA	Occupational Safety and Health Administration
PI	Principal Investigator
PrEP	Pre-Exposure Prophylaxis
QA	Quality Assurance
QNS	Query and Notification System
RA	Research Assistant
SE Model	Supported Employment Model
SAEs	Serious Adverse Events
SID	Study Identification Number
SMC	Study Monitoring Committee
SPSS	Statistical Package for the Social Sciences
STI	Sexually Transmitted Infections
T1	Baseline study visit
T2	Post-Intervention study visit
T3	Month 8 follow-up visit
UC	University of Chicago
UEs	Untoward Events
UNC	University of North Carolina
YMSM	Young Men Who Have Sex with Men
YTW	Young Transgender Women

STUDY ABSTRACT

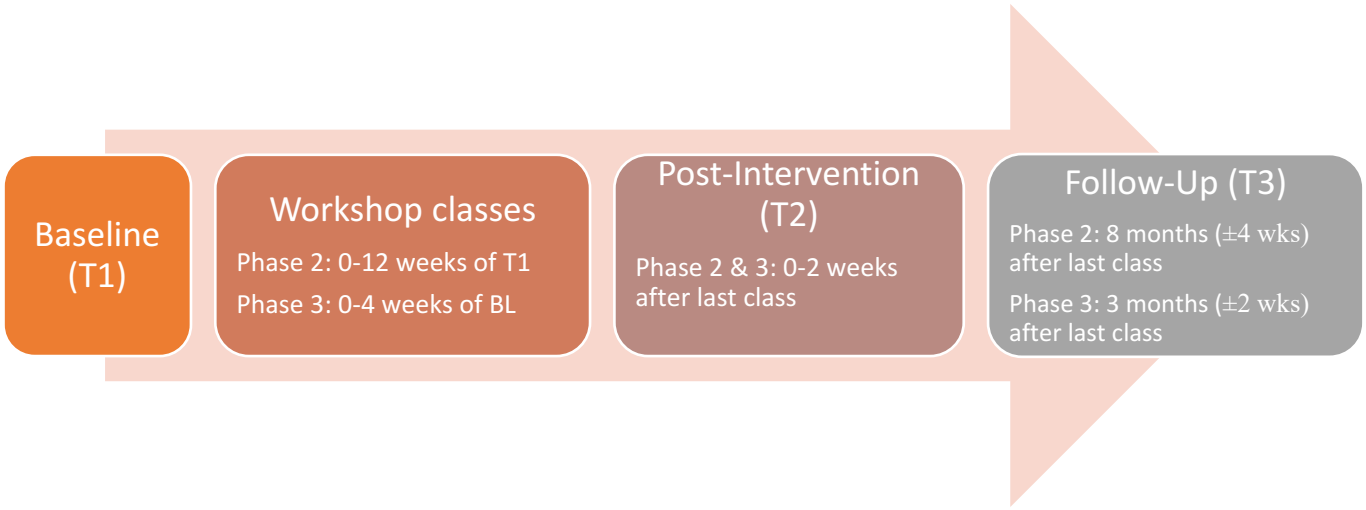
DESIGN:	Work2Prevent will advance the science by adapting, tailoring, and pilot-testing a novel social and structural-level HIV intervention for YMSM and YTW of color ages16-24 aimed at increasing economic stability (i.e., employment) through youth empowerment and asset development, and decreasing HIV risk behaviors (i.e., sex work) associated with social and economic marginalization.
DURATION:	Pilot-testing will last approximately 22 months
POPULATION:	All focus group, pilot-test, and the majority of key informant interview study participants will be Black/African American and/or Hispanic/Latinos males and transgender women (those assigned male at birth), ages 16-24 who identify as either: (1) a man who has sex with men (MSM) and/or gay or bisexual man; or (2) a transgender woman and/or transsexual male-to-female/transwoman. Additionally, key informant interview study participants will be any race/ethnicity and sex/gender, but will be identified as an employer and/or hiring manager of an LGBT-inclusive company.
STUDY INTERVENTION:	Intervention will consist of a series of 4 workshops that promote job seeking self-efficacy and job readiness. These workshops will be adapted from the existing iFOUR curriculum, a job readiness program for transwomen developed by the Chicago House. The iFOUR curriculum will be adapted based on feedback from the CAB, focus groups, and key informant interviews.
DATA COLLECTION:	Data will be collected through transcribed, digital audio-recorded interviews, ACASI, and eCRFs.
PRIMARY OBJECTIVES:	Determine the essential components of a theoretically-driven and developmentally-appropriate employment intervention aimed at increasing job seeking self-efficacy and readiness among YMSM and YTW of color ages 16-24.
SECONDARY OBJECTIVES:	Review and adapt relevant intervention components from the existing evidence-based employment program for HIV-positive adults (iFOUR) to YMSM and YTW of color.
TERTIARY OBJECTIVES:	Refine and pilot-test the employment intervention. Refine and Pilot-test the intervention in community-based settings.
RISK/BENEFIT CATEGORY:	Minimal
MONITORING:	Routine team monitoring of any adverse impact of the study will rely on the ATN Protocol Query & Notification System, a real-time, web-based interactive reporting system. Sites will also record and enter in the study database, all untoward events associated with

study participation, which will be reviewed on the protocol team's implementation monitoring calls.

STUDY SCHEMA



STUDY VISITS



1.0 INTRODUCTION

1.1 Background

Young men who have sex with men (YMSM) and young transgender women (YTW) face enormous disparities. In particular, HIV risk and infection among YMSM and YTW remains a significant public health problem. Furthermore, YMSM and YTW experience social and economic marginalization, which leads to high rates of unemployment, sex work, drug use, homelessness, and HIV risk. Sex in exchange for money, drugs, and/or food among YMSM and YTW of color is a significant public health problem. Adolescent sex work places YMSM and YTW at increased risk for STIs, HIV, poor mental health outcomes, and substance abuse. Interventions that trace and disrupt the pathways between social and structural determinants of HIV infection are needed. Structural-level interventions foster agency to allow individuals to act in their own and their communities' best interests, and have been positively associated with the uptake of behavioral and biomedical technologies, as well as the promotion of health-enabling environments. To date, few structural interventions targeting adolescent sexual and gender minorities exist, and we know of no studies that have explicitly examined the role of employment on HIV risk and prevention for YMSM and YTW. Employment as prevention has the potential to be a scalable intervention that can be deployed among at-risk YMSM and YTW.

In the US, YMSM and YTW, experience high rates of HIV infection (CDC, 2012, 2013; Herbst et al., 2008). In 2010, YMSM, including YTW, age 13-24 represented 19% of all new HIV infections, and 72% of infections among adolescents (CDC, 2012). However, such disparities cannot be attributed to individual-level risk alone, but are situated within larger social and structural contexts that proximate YMSM and YTW of color to increased HIV exposure (Baral et al., 2013; Bauer, Travers, Scanlon, & Coleman, 2012; Brennan et al., 2012; Garofalo, Osmer, Sullivan, Doll, & Harper, 2006; IOM, 2011; Operario & Nemoto, 2010). Despite advancements in LGBT rights, LGBT people face persistent stigma, discrimination, and victimization in school, the workplace, housing, and health care (Melendez et al., 2006; Santos et al., 2014). Such inequities are met with limited legal protections as few state laws specifically protect LBGT people. As a result, a fair majority of YMSM and YTW of color live in poverty, experiencing high rates of homelessness, unemployment, and limited access to health and HIV services(Bradford, Reisner, Honnold, & Xavier, 2013; Gayles, Kuhns, Kwon, Mustanski, & Garofalo, 2016; Meyer, 2003; Millett et al., 2012; Santos et al., 2014; Sevelius, Patouhas, Keatley, & Johnson, 2014).

Faced with few economic options and protections, YMSM and YTW may migrate to non-traditional economies or "street careers" as a means of survival. In a study conducted by Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) members in Los Angeles (Belzer) and Chicago (Garofalo) [Co-I for this proposal], 76% of 151 YTW ages 15-24 reported engaging in sex work, with 35% in the past 3-months(Auerbach, Parkhurst, & Caceres, 2011; Xavier, Bobbin, Singer, & Budd, 2005). Among HIV-positive YTW, 23% were involved in sex work—underscoring the link between adolescent sex work and HIV (Xavier et al., 2005). In a large study of YMSM of color (n=3,316, median age 19), roughly 12% reported engaging in sex work (past 6-months) (Melendez & Pinto, 2007). Sex work and HIV risk are further complicated by drug and alcohol abuse (Gayles et al., 2016). Scalable, low-cost, but potentially high impact, **structural-level interventions** that trace and disrupt the pathways between social and economic marginalization and adolescent HIV infection are sorely needed (Clements-Nolle, Marx, & Katz, 2006; Kammerer, Mason, Connors, & Durkee, 2001; Lomabrdi, Wilchins, Priesing, & Malouf, 2002). Structural interventions, such as comprehensive sex education, universal condom access, clean syringe exchange, and increased healthcare coverage have significantly reduced the incidence of HIV (Bockting, Miner, Swinburne Romine, Hamilton, & Coleman, 2013; Bradford et al., 2013; Clements-Nolle et al., 2006; Durso, Kastanis, Wilson, & Meyer, 2013; Grant et al., 2011; Kammerer et al., 2001; Lomabrdi et al., 2002; Reisner, Bailey, & Sevelius, 2014). The objective of the proposed study is to

target economic stability (i.e., employment) as a structural-level intervention for preventing adolescent HIV. The proposed study will adapt and pilot-test an effective theoretically-driven, employment program for HIV-positive adults (iFOUR) (*A Broken Bargain for LGBT Workers of Color*, 2013; Dyer et al., 2013; Fletcher, Kisler, & Reback, 2014; Kipke, Weiss, & Wong, 2007; Sifra Quintana, Roshenthan, & Krehely, 2010; Wilson et al., 2009) to the needs of at-risk YMSM and YTW of color, ages 16-24. This proposal is responsive to the NIH HIV/AIDS high priority topic by developing, testing, and implementing a new strategy to improve HIV prevention.

1.2 Rationale

The goal of this project is to adapt, tailor, and pilot-test a novel social and structural-level HIV intervention for YMSM and YTW of color aimed at increasing economic stability (i.e., employment) through youth empowerment and asset development, and decreasing HIV risk behaviors (i.e., sex work) associated with social and economic marginalization.

The specific aims of this project are to:

1. Determine the essential components of a theoretically-driven and developmentally-appropriate employment intervention aimed at increasing job self-efficacy and readiness among YMSM and YTW of color ages 16-24.
2. Review and adapt relevant intervention components from the existing evidence-based employment program for HIV-positive adults (iFOUR) to YMSM and YTW of color.
3. Refine and pilot-test the employment intervention.
4. Refine and pilot-test the employment intervention in community-based settings

2.0 STUDY OBJECTIVES

2.1 Primary Objective

The primary objective is to determine the essential components of a theoretically-driven and developmentally-appropriate employment intervention aimed at increasing job seeking self-efficacy and readiness among YMSM and YTW of color ages 16-24. Up to 10 focus groups with YMSM and YTW of color who are currently employed or unemployed but seeking employment will inform the adaptation of the intervention. Key informant interviews with YMSM of color, YTW of color, and LGBT-inclusive employers will address intervention content.

2.2 Secondary Objective

The secondary objective is to review and adapt relevant intervention components from the existing evidence-based employment program for HIV-positive adults (iFOUR) to YMSM and YTW of color. The study will assemble a community advisory board (CAB) of YMSM and YTW of color, youth-serving vocational specialists, employment training and placement experts, and sexual health educators to advise the investigative team on the translation of qualitative findings into curriculum adaptations.

2.3 Tertiary Objective

The tertiary objective is to refine and pilot-test the employment intervention. All qualitative findings will be incorporated into a protocol with the iterative feedback of the CAB. Next, we will pre-test the Baseline visit, workshop sessions, and Post-Intervention visit with a sample of up to 5 participants. We will pilot-test the entire intervention among up to 70 at-risk YMSM of color and YTW of color and then in community-based settings with up to 40 at-risk YMSM of color and YTW of color in a single-arm pre/post trial,

assessing feasibility and acceptability. Study outcomes include: (1) job seeking self-efficacy and readiness; (2) employment; (3) HIV risk behaviors; and (4) STI and HIV infections.

2.4 Study Hypotheses/Research Questions

We hypothesize that this intervention will be both feasible and acceptable to the target populations and that the intervention will increase job self-efficacy and readiness, as well as decrease HIV risk behavior. This study will lead to a final intervention manual to be tested in an R01-type, large multi-site trial across the ATN study sites.

3.0 STUDY DESIGN

All research activities except for the community-based pilot will occur at the University of Chicago (UC), Center for Interdisciplinary Inquiry and Innovation in Sexual and Reproductive Health (Ci3). Ci3 is a foundation and federally funded research center focused on advancing adolescent sexual and reproductive health and rights through innovative research methodologies, intervention strategies, and novel solutions to broad social problems. Ci3 has a dedicated research team skilled in cross-disciplinary collaboration focused on adolescent health along with a broad network of community partners working with LGBT adolescents, and environments that will support the successful development, implementation, and evaluation of the project.

Community-based pilot-testing will be conducted by study staff in the community at the following organizations:

- The Village (Chicago Center of HIV Elimination, University of Chicago)
- TaskForce Prevention and Community Services
- Ann & Robert H. Lurie Children's Hospital of Chicago

Each community setting has a private area for the confidential conduct of the study, including study visits and workshop sessions.

Conceptual Model: Our conceptual model (Figure 1) draws on the existing iFOUR theoretical framework that operationalizes the Health Belief Model (HBM) and the Supported Employment Model (SE) to hypothesize the potential relationship between adolescent employment and HIV risk. We propose that employment, and subsequent economic connection and stability, serves as a structural-level intervention for adolescent HIV. Based on prior research, we hypothesize that the adapted and tailored iFOUR intervention will facilitate increased job seeking self-efficacy and job readiness [Path A] and ultimately increase employment placement and maintenance [Path B]. Further, we hypothesize that establishing economic stability will decrease engagement in HIV risk behaviors and increase HIV prevention and care [Path C], and decrease involvement with known social determinants of HIV (e.g., sex work, drug abuse) [Path D], that are directly linked to HIV transmission and acquisition [Paths E & F] among YMSM and YTW of color.

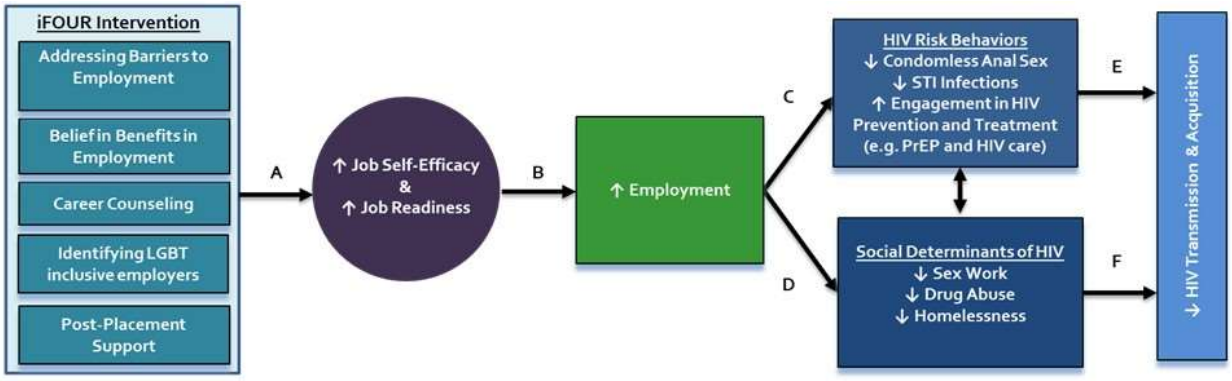


Figure 1. Conceptual Model

3.1 Study Population

All focus group, pilot-test, and the majority of key informant interview study participants will be Black/African American and/or Hispanic/Latinos males and transgender women (those assigned male at birth), ages 16-24 who identify as either: (1) a man who has sex with men (MSM) and/or gay or bisexual man or (2) transgender woman and/or transsexual male-to-female/transwoman. Additionally, key informants and study participants will be any race/ethnicity and sex/gender, but will be identified as an employer and/or hiring manager of an LGBT-inclusive company. Targeted Planned Enrollment tables contain the detailed breakdown for each recruitment and enrollment activity (Appendix III).

3.2 Sample Size

Focus Groups: We will recruit up to 80 YMSM and YTW of color, ages 16-24, to participate in one of up to 10 focus groups.

Key Informant Interviews: We will recruit up to 64 key informant YMSM (n=up to 12), YTW (n=up to 12), and LGBT-inclusive employers (n=up to 40) to participate in key informant interviews.

Community Advisory Board: Up to 12-member CAB of YMSM, YTW, youth-serving employment and vocational specialist, LGBT employment training and placement experts, and sexual health educators.

Intervention Pre-Test: We will pre-test the adapted employment intervention with a small sample of up to 5 YMSM of color and YTW of color.

Intervention Pilot-Test: We will pilot-test the adapted employment intervention with a diverse sample of up to 70 YMSM of color and YTW of color.

Community Pilot-Test: We will test the intervention with a sample of up to 40 YMSM of color and YTW of color in community-based settings.

3.3 Outcome Measures

Study outcomes include: (1) job seeking self-efficacy and readiness; (2) employment; (3) HIV risk behaviors; and (4) STI and HIV infections.

3.4 Biological Specimens

Project staff members who have completed mandatory training will conduct HIV/STI testing. Study participants will be screened for drug use and STIs such as chlamydia, gonorrhea, syphilis, and HIV

infection at the baseline and follow-up visits. Clinical specimens may include 15-20 mL first-catch urine, anal swab (GC,CT), oral/laryngeal swab, and finger stick. Participants with reactive STI or HIV tests will be referred to affiliated clinics at each site for evaluation and treatment. All participant referral clinics will be comprehensive and follow the Ryan White HIV/AIDS Programming instruction as developed by the HRSA HIV/AIDS Bureau. Senior Investigators are practicing physicians at study referral sites with experience in YMSM and YTW health, and will provide any subsequent mental health, medical case management, and psychosocial support service referrals as needed for participants. Following the protocols of our previous studies involving HIV testing, HIV-positive participants at follow-up will not receive HIV testing if they produce documentation of a previous diagnosis (e.g., medications, lab report). In addition, phase 3 participants with a known HIV positive status at the time of consent will not receive HIV testing at baseline or follow-up.

4.0 SELECTION AND ENROLLMENT OF STUDY PARTICIPANTS

4.1 Inclusion Criteria

4.1.1 Focus Group Inclusion Criteria

Must meet the following six criteria:

1. Male or assigned male at birth (YTW)
2. Identify as a man who has sex with men (YMSM) and/or gay bisexual man or transgender woman/transwoman
3. Identify as African American/Black, Hispanic/Latino, and/or a racial/ethnic minority or person of color
4. 16-24 years old
5. English-speaking (primary)
6. One of the following:
    a. Currently employed
    b. Unemployed but seeking employment

4.1.2 Key Informant Interviews Inclusion Criteria for YMSM and YTW

Must meet the following six criteria:

1. Male or assigned male at birth (YTW) [YMSM/YTW only]
2. Identify as a man who has sex with men (YMSM) and/or gay bisexual man or transgender woman/transwoman
3. Identify as African American/Black, Hispanic/Latino, and/or as a racial/ethnic minority or person of color
4. 16-24 years old
5. English-speaking (primary)
6. One of the following:
    a. Currently employed
    b. Unemployed but seeking employment

4.1.3 Key Informant Interviews Inclusion Criteria for LGBT-Inclusive Employers

Must meet the following four criteria:

1. Employers and/or managers at LGBT-inclusive companies which:

   a. Scored 80% or higher on the Human Rights Campaign, Corporate Equality Index 2015-2016 or
   b. Is a company currently listed as an Out & Equal, LGBT CareerLink employer or
   c. Is a non-profit organization with an LGBT-focused mission or
   d. Is an LGBT-owned small business (<200 employees) or
   e. Is a company or organization participating in an LGBTQ job fair
2. Located in the Chicago area
3. English-speaking
4. 18 years or older

4.1.4 Phase 2 Intervention Pre Test & Pilot-Test Inclusion Criteria

Must meet the following eight criteria:

1. Male or assigned male at birth (YTW)
2. Identifies as a man who has sex with men (YMSM) and/or gay bisexual man or transgender woman/transwoman
3. Identifies as African American/Black, Hispanic/Latino, and/or as a racial/ethnic minority or person of color
4. 16-24 years old
5. English-speaking (primary)
6. HIV negative or of unknown status
7. Currently unemployed but seeking employment or employed only part-time 35 hrs or less on avg/wk)
8. Able to attend a 4-session employment program

4.1.5 Phase 3 Community Pilot Inclusion Criteria

Must meet the following eight criteria:

1. Male or assigned male at birth (YTW)
2. Identifies as a man who has sex with men (YMSM) and/or gay bisexual man or transgender woman/transwoman
3. Identifies as African American/Black, Hispanic/Latino, and/or as a racial/ethnic minority or person of color
4. 16-24 years old
5. English-speaking (primary)
6. Currently unemployed but seeking employment or employed only part-time 35 hrs or less on avg/wk)
7. Able to attend a 4-session employment program
8. Did not participate in Phase 2 pilot

4.2 Exclusion Criteria

4.2.1 Focus Groups

Must not meet any of the following:

1. Individuals identify as non-Hispanic White
2. Individuals not assigned male at birth

4.2.2 Community Advisory Board Exclusion criteria:

Must not meet any of the following:

1. Under age 18
2. White, Asian, Native American, and any other ethnic group not Black or Latino

There are no exclusions regarding sex/gender for the Community Advisory Board.

4.2.3 Intervention Pilot-Test Exclusion Criteria

Must not meet any of the following:

1. Individuals identify as non-Hispanic White
2. Individuals not assigned male at birth
3. Phase 2 only: Individuals with a known HIV positive-status at baseline

4.3 Recruitment and Screening

Recruitment. Study participants will be recruited by research assistants (RAs) and study recruiters who are also members of the target population. For the CAB, focus groups, and key informant interviews, participants will be recruited by the RAs through pre-existing network connections, including the Chicago Center for HIV Elimination and snowball sampling. Planned recruitment strategies for LGBT-Inclusive Employers also include attending LGBTQ job fairs and emailing LGBTQ non-profits, LGBTQ-owned small businesses, and employers in the Human Rights Campaign Corporate Equality Index or Out & Equal, LGBT CareerLink lists.

For the pilot interventions, participants will be recruited actively by RAs and study recruiters in primary and community clinics serving YMSM and YTW of color, and local gathering places and events for YMSM and YTW such as night clubs, House & Ball events, and other public places that serve the LGBT community (e.g., LGBT centers). Additionally, participants will be asked to refer friends or acquaintances that may be eligible. Passive recruitment will include posting study flyers and posters, and describing the study on Facebook and other social media websites.

4.4 Informed Consent

Consent Process. Eligible study participants will be taken through the informed consent process in a private room. RAs will review the consent process to make a formal assessment of the participant's decisional capacity to consent prior to signing using a 2-step process. First, the RA will determine if the person understands the study goals by asking "Can you tell me what this study is about?" In step 2, potential participants will be asked questions designed to assess their capacity to understand, appreciate, reason with, and express a choice about participation in our specific protocol. Participants are asked to: (1) name things they will be expected to do during the study; (2) explain what they would do if they no longer wished to participate in the study; (3) explain what they would do if they experienced distress during the study; and (4) identify potential risks for participating in the study. Respondents will be enrolled only if they are able to provide clear and correct answers to each of these items. If study staff feels there is a question about the need for a more formal assessment of the decisional capacity of a potential participant, they will contact the Project Lead or other senior staff. Additionally, study staff will inform the person that the research study is voluntary and their decision whether or not to participate will not impact their relationship with the research site or any subsequent participation in research studies or care provided by the study site. If they agree to participate, they will be immediately enrolled in the study (Appendix VI).

Parental Consent. We will not require parental consent for study enrollment and participation. Parental consent may decrease participation rates because some youth will fear that they may be "outed" as a result of participation. Disclosure of sexual orientation or gender identity may place participating youth at risk for parental harassment, abuse or expulsion from the home. The nature and scope of the proposed research do not pose more than "minimal risk" to participants (45 CFR Part 46.102): "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." Study measures are standard in this population, as are waivers of parental permission for survey and interview studies. Additionally, risk behavior assessments will be based on the National Youth Risk Behavior Survey 2015, which has been administered to youth in 9th to 12th grade. HIV/STI testing is also common (and encouraged) among this group, and does not require parental permission or notification in the state of Illinois.

To compensate for waiver of parental consent participants receive a formal individual assessment of capacity to consent (above) to ensure their understanding of study goals, procedures, and risks from disclosure of sensitive information (see Consent Process). Consistent with national policy recommendations from the Society for Adolescent Medicine, requiring parental permission for the proposed study would have a number of possible negative effects, including: (1) reducing the validity of the findings by effectively eliminating potential participants unwilling to share permission forms with their parents/guardians; (2) increasing risk to some youth whose parents have a negative response to the material in the permission forms that would (correctly) suggest their child has a minority or alternative gender identity; and (3) adding little in the way of actual subject protection, given the minimal risk of study participation.

4.5 Contact Information

Once consented, 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, and if messages can be left at or texted to the numbers provided. Study staff will not leave or send messages unless expressly permitted to do so by the. If permission is given to leave phone messages, site staff will assure participants that any 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

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

5.0 STUDY PROCEDURES

Aim 1: Determine the essential components of a theoretically-driven and developmentally-appropriate employment intervention aimed at increasing job seeking self-efficacy and readiness among YMSM and YTW of color ages 16-24. Two formative assessment strategies will be used to determine the essential components of the employment intervention: (1) focus groups and (2) key informant interviews (Aim 1). First, focus groups be conducted with currently employed and unemployed (but seeking employment) YMSM and YTW. The goal of the focus groups will be to

explore and identify the following: perceived barriers to employment, beliefs in the benefit of employment, and career counseling needs of YMSM and YTW. Additionally, key components, including potential models of the adapted iFOUR employment curriculum will be shared and discussed with participants in order to gauge relevance and potential modifications for the target population. Next, we will conduct key informant interviews with YMSM, YTW, and LGBT-inclusive employers. The goal of this phase of formative research will be to hone and identify key areas related to barriers and facilitators to hiring and retaining YMSM and YTW: YMSM and YTW career readiness, identifying an inclusive employer, and post- placement support necessary to retain YMSM and YTW (Appendix II example interview guide).

Focus Groups: Recruitment and Enrollment. We will recruit up to 80 YMSM and YTW of color, ages 16-24, to participate in one of up to 10 focus groups .

Key Informant Interviews: Recruitment and Enrollment. We will recruit up to 64 key informant YMSM (up to 12), YTW (up to 12), and LGBT-inclusive employers (up to 40) to participate in key informant interviews. Over 35 major corporate employers in Chicago have a Corporate Equality Index of 100% (e.g., Groupon, Inc., McDonalds Corp., etc) (HRC, 2015).

Aim 2: Review and adapt relevant intervention components from the existing evidence-based employment program for HIV-positive adults (iFOUR) to YMSM and YTW of color.

Convene a Community Advisory Board (CAB). Up to a 12-member CAB of YMSM, YTW, youth-serving employment and vocational specialists, LGBT employment training and placement experts, and sexual health educators will be led by Dr. Hill and the investigative team. Members of the CAB will meet no less than 20 times over the course of the project to review and interpret qualitative findings into distinct curriculum adaptations. The CAB will be instrumental in providing information on curriculum content, appropriateness, cultural sensitivity and specificity, study methodology, and best methods for enhancing participation, as well providing ongoing feedback and interpretation of data. The CAB will ensure that the adaptations reflect YMSM's and YTW's experience and employment needs (Aim 2).

Aim 3: Refine, pre-test, and pilot-test the employment intervention. In order to achieve Aim 3, we will incorporate all qualitative findings and refine the final intervention curriculum modules using additional feedback from the CAB. In addition, the CAB will assist with Phase 2 by pre-testing and providing feedback on Phase 2 data collection instruments.

The adapted employment intervention will first be pre-tested (Baseline, workshops, Post-intervention) with an initial sample of up to 5 participants in order to test the implementation of assessments and workshop activities. Refinement to workshop activities will be considered if activities do not fit within the session time-period or participants do not understand or comprehend the activity.

Next, the intervention pilot-test of the final adapted employment intervention will be completed with a diverse sample of up to 70 YMSM and YTW, ages 16-24, in a single-arm longitudinal pre/post study of the employment intervention to evaluate *feasibility, acceptability,* program *satisfaction,* and preliminary *efficacy* using assessments at Baseline (T1), Post-Intervention (T2), and 8 Months Follow-Up (T3).

Aim 4: Refine and pilot-test the intervention in community-based settings. In order to achieve Aim 4, we will refine the procedures and intervention so that it may be conducted within community-based settings in order to further test the implementation of assessments and workshop activities in Phase 3.

The adapted employment intervention will be completed with a diverse sample of 40 YMSM and YTW, ages 16-24, in a single-arm longitudinal pre/post study of the employment intervention to evaluate *feasibility, acceptability,* program *satisfaction,* and preliminary *efficacy* using assessments at Baseline (T1), Post-Intervention (T2), and 3 Months Follow-Up (T3).

5.1 Intervention Enrollment Procedures

An ATN Study Identification number (SID) will be assigned by the site staff in consecutive order from the Carolina Data Acquisition and Reporting Tool (CDART).

5.2 Intervention/Investigation Procedures

Up to 70 participants will be enrolled for the intervention pilot part of phase 2 and up to 40 participants for phase 3. Participants will complete a 4 session workshop. Workshops will be in groups of 6-12. These workshops will be based on the pre-existing iFOUR program (description below) with modifications based on CAB, focus group, pre-test, and interviewer feedback.

iFOUR

The Increase Individual Income and Independence program (iFOUR) is an employment program that was developed over ten years ago to target the employment needs of HIV- positive people. The program was based on the Supported Employment framework that was developed to help connect people with a range of disabilities (physical and cognitive) to employment because of the benefits of employment, both monetary and non-monetary. Thus, researchers at the University of Illinois-Chicago collaborated with Chicago House, a housing and support organization for HIV- positive individuals, to develop a Supported Employment program for HIV- positive individuals. Like Supported Employment, iFOUR provides a variety of supports to aid in participants' job success, such as job training referrals, client-tailored job placement, post-employment assistance, and benefits planning. The program includes regular interviews to evaluate program outcomes, such as medication adherence, use of drugs and alcohol, and assessments of physical and mental health. Since 2005, the iFOUR program has been refined to better tailor to the needs of HIV- positive individuals, including the addition of one-on-one work with a career specialist. These specialists assess job readiness and are trained in the impact of HIV/AIDS on employment, so as to best assist participants with their career aspirations. They also assist with linking participants to additional educational resources and provide support with interview preparation and development of resumes and cover letters. iFOUR also includes a four-week training workshop that is tailored to the needs of HIV-positive participants, dealing with questions such as workplace discrimination, benefits maintenance, and the relationship of health beliefs and work. The workshop also covers confidence and communication skills, while highlighting the non-monetary benefits of employment. The iFOUR program has had positive outcomes for participants, documented in several studies (Appendix IV). The goal of the current study is to tailor then pilot test the iFOUR program for individuals who are HIV-negative but at high-risk for acquiring HIV.

5.2.3 Research Staff Training

Prior to engaging in any study specific activities, staff must complete study trainings as outlined below:

- GCP training
- Human Subjects Protection training
- W2P Workshop Facilitator Training: Members of the research team who facilitate workshop sessions will be trained by staff who have run the iFOUR program. This training includes an overview of how iFOUR was implemented, challenges in implementation, and best practices for ensuring the utility of career readiness training.
- Title IX Training: All staff will complete annual Title IX training in the prevention of sexual assault and sexual misconduct via “Intersections: Preventing Harassment and Sexual Violence”
- Suspected Child Abuse Reporting Training: All staff will review guidelines related to their status as mandated reporters of suspected child abuse and neglect if applicable by state law. Additionally, staff may opt to complete the web-based training “Recognizing and Reporting

Child Abuse: Training for Mandated Reporters," which defines when mandated reporters must contact Child Support Services if abuse or neglect is suspected.

- HIV Testing Training: Staff engaged in the collection of biological samples will complete a 4 hour specialized training on HIV client-centered counseling techniques, HIV prevention strategies, and other sensitive issues through the Midwest AIDS Training and Education Center.
- Ready Set PrEP! Training: All staff will complete training regarding HIV prevention and PrEP access through the AIDS Foundation of Chicago's (AFC) "Ready Set PrEP!" This training focuses on how antiretroviral medication can be used for prevention of HIV transmission and how social determinants of health impact PrEP access.

5.2.4 Intervention Monitoring/Quality Control

Research staff running the workshops will complete fidelity assessments during administration of each workshop class to help ensure and evaluate homogeneity across workshop groups. In addition, workshop staff will conduct a debriefing session after the administration of each workshop class in order to note any issues or observations.

6.0 EVALUATIONS AND MEASURES

The study procedures will unfold in three phases, outlined below.

Phase 1

Focus groups and key informant interviews will be conducted. Focus group participants will be asked to discuss perceived barriers to employment, beliefs in the benefits of employment, and career counseling needs of YMSM and YTW of color. Participants will also be asked to review key components of models of the adapted iFOUR employment curriculum to gauge relevance and potential modifications. Key informant interviews will be conducted and the topics covered in will be similar to the focus groups, while allowing for more in-depth investigation of individual experiences.

Phase 2

Based on the data collected during phase 1, we will develop the adapted employment intervention and complete an initial pre-test consisting of the Baseline visit, workshops, and Post-Intervention visits. We will then pilot the intervention with participants in a single-arm longitudinal pre-/post-study. At Baseline, participants will complete a 30-60 minute audio-computer assisted self-interview (ACASI) survey covering sociodemographics, employment variables, HIV risk behavior variables, and potential modifying variables. Participants will also be asked for biological specimen collection for HIV/STIs screening and drug testing (such as urine, oral/laryngeal swab, finger stick, and anal swab). Upon completion of the employment intervention at Post-Intervention, participants will be asked to complete a second 30-45 minute ACASI survey regarding employment variables, HIV risk behavior variables, as well as the feasibility, acceptability and satisfaction of the program. After 8 months post-intervention, participants will be asked to return to the study site to complete the Follow-Up visit and repeat ACASI survey assessing sociodemographics, employment variables, HIV risk behavior variables, and potential modifying variables, as well as to provide repeat biological specimens for HIV/STIs screening and drug testing.

Phase 3

We will further adapt study procedures and the employment intervention so that it may be administered in community-based settings. All study procedures for Phase 3 are same as Phase 2 except that the Follow-Up visit is at 3 months follow-up, and the ACASI surveys are shorter in length at 20-45 minutes each visit.

6.1 Pilot-Test Screening

Interested participants will be pre-screened for eligibility by the ATN 151 Screening Form, either via phone with study staff or online via a Qualtrics survey. Participants who are eligible at pre-screen will then be scheduled for their Baseline study visit.

After informed consent, participants will be assigned a SID and then asked items from the ATN 151 Eligibility Form to confirm that the participant meets study criteria.

Table 1: Description of variables to be collected at each of the three study time points.

Study visits	**Variables collected**
Baseline Visit (T1)	Sociodemographics, employment variables, HIV risk behavior variables, and potential modifying variables HIV/STI screening and drug testing
Workshop Intervention	Workshop fidelity and debriefing
Post-Intervention Visit (T2)	Employment variables, variables assessing feasibility, acceptability, and satisfaction of intervention, and HIV risk behavior variables
Follow-up Visit (T3) Phase 2: 8 Months Phase 3: 3 Months	Sociodemographics, employment variables, HIV risk behavior variables, and potential modifying variables HIV/STI screening and drug testing

6.2 Baseline/Enrollment

After informed consent and eligibility has been confirmed, participants will undergo biological specimen collection for HIV/STIs screening and drug testing. Please note that for Phase 3, if a participant has a known positive HIV status they will not undergo HIV testing. Participants will be given an iPad tablet and headphones and asked to complete an ACASI survey. The survey includes items on: sociodemographics, employment variables, HIV risk behavior variables, and potential modifying variables including perceived transgender discrimination scale, job seeking self-efficacy, managing interview, resilience, employment and job search, integrated motivations, internal self-concept, goal internalization, perceived social support, drug use, alcohol use, sexual history, commercial sex work, homelessness, condom intentions, money inventory, and PrEP awareness.

6.3 Workshop Intervention

After the Baseline visit (T1), participants have up to 12 weeks to complete workshop classes for Phase 2 and up to 4 weeks for Phase 3, otherwise they will go on to complete the T2 and T3 visits. Participants who do not complete any workshop classes may still complete the T3 visit.

6.4 Post-Intervention

At the completion of the workshop intervention, participants have 0-2 weeks to complete the post-intervention visit (T2). Participants will complete an ACASI survey assessing the feasibility, acceptability, and satisfaction of the program, as well as employment variables such as perceived discrimination, job self-efficacy, managing interviews, resilience, employment and job searching, motivations, goal setting, financial planning, and variables such as perceived social support, drug and alcohol use, sexual history, sex work, housing situation, condom use, and HIV risk behaviors.

6.5 Intervention Follow-Up

For Phase 2 the follow-up visit (T3) is scheduled for 8 months post-intervention (±4 weeks), and for Phase 3 the follow-up visit is scheduled for 3 months post-intervention (±2 weeks). At this visit, participants will repeat biological specimen collection for HIV/STIs screening and drug use. If a participant already has a known positive HIV status they will not undergo HIV testing. Participants will repeat the ACASI survey with items on sociodemographics, employment variables, HIV risk behavior variables, and potential modifying variables such as perceived transgender discrimination scale, job seeking self-efficacy, managing interview, resilience, employment and job search, integrated motivations, internal self-concept, goal internalization, perceived social support, drug use, alcohol use, sexual history, commercial sex work, homelessness, condom intentions, money inventory, and PrEP awareness.

7.0 DATA COLLECTION AND SITE MONITORING

7.1 Development of Protocol and Case Report Forms

The ATN CC, in collaboration with the Protocol Team, is responsible for the development of this protocol as well as the Case Report Forms (CRFs) and Audio Computer-Assisted Self Interview (ACASI). All CRFs for this study will be available for download from the ATN study website.

7.2 Data Records

Participant-related study information will only be identified through a SID which will be on all participant CRFs and ACASI response files. Participant names or other personally-identifying information will not be used on any study documents except that contact information approved by the study participant will appear on study contact forms and reports, which will be securely maintained by both the site and the CC. All study-related information will be kept in double-locked, limited access areas at the study site. A log that links the names of participants to their SID number will also be kept under double locks and separate from all other research records, accessible only to the study staff, ATN site monitors, and representatives from the NICHD. Original source documents for individual participants will be maintained at the study site and will be accessible only to the study staff. Data from original source documents will be transcribed on CRFs as applicable.

Individuals who complete the pre-screening process but who do not consent to participate will only have information collected on the ATN 151 Screening Form, which will be entered into the study database using a method to maintain anonymity.

7.3 Data Collection and Submission

Research staff will be responsible for ensuring that CRF data is entered into CDART within one calendar week of data collection in a timely manner. Data edits through range checks and field inconsistencies will

be built into the CDART database to enable real time correction of key entries and CRF completion errors.

All data collected using ACASI will be developed within the CDART web-based system. The participant's SID will be used in order to link the interview responses to the participant's CRF data. The ACASI data will be collected on Apple iPad devices using Qualtrics and the CDART data management tool. Data are stored on secure servers maintained by the ATN CC. No data is written to the iPad hard drive. Since data are persisted to the secure servers during data collection, if a network failure occurs during an interview little to no data will be lost. The secured servers comply with FIMSA regulations and are tightly controlled, and inaccessible to any person or application without appropriate credentials.

Focus group and key informant interviews will be digitally audio-recorded with participant consent. Immediately upon completion, the digital audio files will be uploaded to a secure server. The audio recordings will be uploaded to a secure website belonging to a transcription company (CastingWords), who will listen to the recordings, transcribe them into a Microsoft Word file, and upload the transcript files to their secure website for download by study staff. Transcripts will be checked against audio recordings for accuracy. Once that process is complete, the audio files will be destroyed. Dr. Hill will ensure that the audio files are destroyed by the transcription company, and permanently deleted from the University of Chicago OBGYN server.

Data from focus groups and key informant interviews will be transferred to the ATN CC. This data and all data collected using CDART will be submitted to the NICHD's Data and Specimen Hub (DASH) after completion of the study in accordance with the NICHD DASH Data Archive Policy (https://dash.nichd.nih.gov/Resource/Policies) and the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/introduction.htm).

7.4 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. ATN sites will specify their QA plan at protocol registration in the Protocol Implementation Plan.

7.5 Role of Data Management

The CC will provide instructions concerning ACASI administration, the recording of study data on CRFs, data entry, and data transmission to the CC via CDART at the completion of the study. It is the responsibility of the CC to assure the quality of computerized data. This role extends from protocol development to generation of the final study databases.

7.6 Study Site Monitoring and Record Availability

Site monitors from the CC will visit participating study sites to review participant records, ICFs, CRFs and supporting source documentation, compliance with the protocol, and the 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., CRFs, ICFs) *and pertinent source 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

Site study staff will track participant study recruitment and retention for all study visits, as well as intervention sessions completed by participants.

8.2 Study Visit Management

After the Baseline visit, participants have up to 12 weeks to complete workshop classes for Phase 2 and up to 4 weeks for Phase 3, otherwise they may go on to complete the post-intervention and follow-up visits as outlined below. Participants who do not complete any workshop classes may still complete the follow-up visit. Participants may withdraw from the study at any time, and may be considered lost to follow up if they are unable to be reached after a minimum of three documented contact attempts.

- For participants that complete all 4 workshop sessions, the post-intervention visit will need to be completed w/in 2 weeks of the last workshop session, otherwise they may go on to complete the follow-up visit at 8 months (±4 weeks) after the last workshop session for Phase 2 and at 3 months (±2 weeks) for Phase 3.
- For participants that complete at least one but less than all four of the workshop sessions in the time allowed (within 12 weeks of baseline for Phase 2, and 4 weeks for Phase 3), the post-intervention visit will need to be completed within 14 weeks of Baseline for Phase 2 and within 6 weeks for Phase 3. Otherwise, participants may go on to complete the follow-up visit at 8 months of the last class completed (±4 weeks) for Phase 2, and 3 months of the last class completed (±2 weeks) for phase 3.
- For participants that do not complete any workshop sessions, the follow-up visit will need to be completed at 8 months (±4 weeks) after Baseline for Phase 2, and 3 months (±2 weeks) for Phase 3.

8.2.1 Completing the Audio Computer Assisted Self-Interview

- 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 iPad in an accommodating, private and quiet area;
- The research staff assists with ACASI tutorials; and
- If the participant requires a break, research staff will make sure the computer program is exited and re-entered properly so that the participant's privacy is maintained

8.2.1 Debriefing and Referral Procedures for Audio Computer Assisted Self-Interview Participants

- 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
- At the completion of the ACASI, the research 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,"* they should be thanked for participation. The respondent will be given contact information for mental health personnel available at UC and informed that they 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

Focus Groups: Participants will receive $40 each for focus group participation.

Key Informant Interviews: LGBTQ-friendly employers will be offered a $10 gift card for key informant interview participation. All other participants will receive $40 for key informant interview participation.

CAB: $30 per meeting.

Intervention Pre-Test: Participants will receive $30 for completing visit surveys at T1 and T2, $40 for providing optional biologic specimens at T1, and $20 per workshop session attended, for a possible total of $180.

Intervention Pilot: Participants will receive $30 for completing visit surveys at each time point, $40 for providing optional biologic specimens at T1 and T3, $40 per workshop session attended, for a possible total of $330.

Intervention Community Pilot: Participants will receive $30 for completing visit surveys at each time point, $40 for providing optional biologic specimens at T1 and T3, and $30 per workshop session attended, for a possible total of $290.

8.4 Intervening on "Social Harms"

8.4.1 Potential risks

Potential risks consist of participants being uncomfortable or emotionally upset as a result of the questions asked in the assessments, and potential breaches of confidentiality. However, participants are allowed to discontinue the study at any time and to not respond to questions they are uncomfortable with, without any penalty. All information disclosed to the research team will remain confidential, even if a participant chooses to withdraw from the study. Additionally, study participants can ask study staff to provide any needed referrals to counselors or other support if they become emotionally upset. Study participants will also have access to a clinician or social worker who can help them address any feelings and/or questions which arise over the course of their participation. The investigative team has conducted studies with hundreds of assessment visits and has managed all visits successfully. Procedures for youth who do experience discomfort are detailed below.

All study records that identify the participant will be kept confidential, however there is a risk of loss of confidentiality such as by mandated reporting of child abuse/neglect for participants 16-17 years old. All healthcare professionals are required by law to report suspected cases of abuse and/or neglect. Although several of the proposed assessment measures include elicit information about experiences of discrimination and sexual behaviors, they do not specifically address child abuse or neglect. Thus, a report of abuse or neglect will only occur if the participant knowingly volunteers this information. In addition,

all participants are told in the consent process that statements of potential harm-to-self or others may require further assessment and/or reporting. The research team has specific procedures in place for referrals and strict confidentiality reporting.

Additionally, a potential risk to confidentiality may occur if a participant tests positive for HIV or an STI during the course of the study. All participants will be told of reporting requirements during the consent process. If a participant tests positive for HIV or an STI, s/he will be referred to the Chicago Center for HIV Elimination (CCHE) for confirmatory HIV testing and appropriate care. CCHE is required to report all new cases of HIV by name and contact information to the Illinois Department of Public Health. Other information, including risk factors and sex contacts, are also requested for partner services. As an additional safeguard, the proposed study has two practicing physicians who have extensive experience treating STIs and HIV/AIDS among YMSM and YTW of color.

There is a general potential risk of a breach in confidentiality of participant information. However, all investigators and study staff have been involved in several local and national studies of YMSM and YTW and have considerable experience implementing measures to protect participant confidentiality. Some of these steps include signed confidentiality agreements, in-service training on confidentiality, and the assignment of study ID numbers for all participants. Additionally, all front-line research staff who will be working with the participants throughout the project will undergo routine ethics training and complete specialized confidentiality training around HIV and other sensitive issues through the Chicago Department of Public Health. All staff will have completed training regarding HIV prevention and PrEP access through the AIDS Foundation of Chicago's (AFC) "*Ready Set PrEP!"* should participants request additional information on these services. All staff will complete the Midwest AIDS Training and Education (MATEC) training and CDC Passport to Partner Services HIV and STI Prevention training prior to implementation. All data will be collected on secure network hosted by the university technology services.

8.4.2 Potential coercion

Any study that pays a stipend may produce coercion. Eliminating the possibility of coercion by not awarding stipends would make it impossible to conduct many studies, and would shortchange subjects who provide time and energy, and may incur costs such as bus, train or cab fares. The resolution to this problem is to ensure that stipends are not inappropriately large, to probe potential subjects to make sure they have not been coerced, and to give persons who may have been coerced the opportunity not to enroll in the study in a manner that will protect them from retribution by the person coercing them. We believe we meet these conditions. The employment program session stipends proposed are similar to other studies used by members of the investigative team, and have not raised issues of coerciveness.

8.4.3 Protection against risk

8.4.3.1 Discomfort or distress during the research

Because there is a potential for discomfort or distress due to the research topic, we will make every effort to create a secure environment (ensuring privacy) prior to conducting baseline and follow-up assessments and intervention sessions. Participants will be told that they do not have to answer any question they do not wish to. Participants experiencing mild distress during the assessments will be offered a small break or will be rescheduled to complete the assessment at a later date. In the unlikely event that a participant experiences considerable distress, we will make a referral (if needed) for clinical assessment and/or counseling provided at each of the primary sites. Participants will be given the names and office phone numbers of the assessor, the Site Lead, and the Project Coordinator, and will be provided with referrals for mental health and support services. The Site Lead will be on-call for any serious problems that arise during assessments and intervention sessions.

8.4.3.2 Disclosure of abuse, homicide or suicide risk

A number of procedures will be taken to minimize risk to participants. The consent procedures will explicitly state that participation in the research is voluntary, and that questionnaires will include items about sexual history, substance use, and sexual risk behaviors. Participants will be informed of the confidentiality of their responses as well as the limits of that confidentiality. If a participant discloses suicidal ideation, any type of violence, or homicidal intent, the research team will assess the level of risk and determine the best course of action (e.g., sending the participant to the emergency room, notifying the police). Youth under age 18 will be informed that disclosure of violence or victimization relating to a family member will require an evaluation by onsite behavioral health staff to determine the best course of action, and that under conditions of immediate danger or harm may require reporting or notification to appropriate authorities (i.e. the police or the Department of Children and Family Services). A determination of the decision-making capacity of the participants will be done prior to obtaining consent and research staff will pay particular attention to participants' understanding of the risks associated with disclosure of information and the implications of that disclosure in accordance with state law.

During all study visits, there will be an on-site behavioral health clinician or social worker to provide clinical backup to the RA, particularly concerning issues of child abuse, neglect, and suicidality. The on-site behavioral health staff will have specific clinical expertise in managing the unique challenges facing young sexual and gender minorities. Consistent with abuse and/or neglect reporting requirements, should a report to the authorities be required, the information provided will be from the Project Lead at each site. No mention of the youth's participation in this particular research project will be disclosed. We will inform participants that criminal behavior (i.e. drug use) is not reported to authorities and that the information is entirely confidential. These procedures will be reviewed in writing and in person by the RA as part of the informed consent process to help youth assess whether they wish to participate in the research, and to minimize the inadvertent disclosure of information. Regardless of age, if a participant discloses suicidal ideation or intent, the behavioral health clinician or social worker will be available to assess the level of risk and to help determine the best course of action (e.g. send to the emergency room).

8.5 Criteria for Premature Discontinuation

Participants may choose to withdraw themselves from the study at any time. The study is voluntary and the alternative to participating in any phase of the study is not participating.

9.0 MONITORING & REPORTING SAFETY EVENTS

Site staff must follow their oversight IRB's procedure for reporting and managing safety events, as well as the ATN CC procedures outlined below and in Chapter 10 of the ATN Manual of Policies and Procedures (MOPP). Safety events are reported using the ATN QNS accessible through the ATN website (https://www2.cscc.unc.edu/atn/). All safety events will be reviewed by the study team and reported to NIH.

9.1 Study Team Review

Given that this study is a short pilot study of a behavioral intervention with a single arm (a pre-/post study), this study will use study team review for clinical research monitoring (CRM), where the study team consists of the Protocol Team at UC, a NIH representative, and the Coordinating Center (CC) at UNC Chapel Hill. Safety events will be reviewed by the study team on a case-by-case basis at team meetings which will occur at least monthly. The members of the study team and data to be reviewed at the meetings are described below.

Study team members:

- Protocol Chair(s)
- ATN Coordinating Center Investigator
- Protocol Manager
- Project Manager
- NIH Representative

During the study team meetings, data quality and participant safety (e.g., number and type of safety events, recruitment and retention) will be reviewed and the team will determine what actions are necessary, if any. The study team will also previously reported safety events for which new information is available.

The CC will monitor accrual and retention based on reports which they will generate monthly. Reports will include accrual, baseline characteristics, data quality, and completeness. If there are any problems with accrual or retention rates at specific sites, the CC will work with the site to identify operational issues or problems and take appropriate action.

9.2 Reportable Safety Events

There are three types of reportable safety events that require expedited reporting in QNS (within 2 reporting days of site awareness):

1. Adverse events (AEs) deemed to be possibly related or definitely related to the study that are severity grade 3 or higher
2. All serious adverse events (SAEs)
3. Untoward events (UEs) deemed to be possibly related or definitely related to the study that are severity grade 3 or higher

Please note that all community UEs (not graded) and UEs grades 1-2, as well as AEs grades 1-2, do not require expedited reporting. These types of events must be reported within 5 reporting days of site awareness, and are up to the discretion of the site investigator and protocol team as to whether or not they are reportable.

Once entered into QNS and after study team review, safety event reports should be printed and filed with participant records (or with regulatory documents if not related to a specific participant). In addition, study staff must also follow their oversight IRB procedures for reporting and managing safety events.

For more information regarding the definitions of each type of safety event and details on reporting, please refer to the ATN CC MOPP Chapter 10.

9.3 Safety Event Reporting Periods

Safety events must be reported throughout the duration of a study. If the event involves a specific study participant, events must be reported for the duration of that participant's enrollment in the study. After the protocol-defined reporting period ends, only events that study staff become aware of on a passive basis (from publicly available information) should be reported.

The duration of the reporting period for community UEs events begins at project start-up and continues through any professional or lay publication of study findings. If the online reporting system is not available after study closure, electronic reports should be made directly to Program Staff at NICHD.

All potential safety events should be reported as soon as possible after site staff become aware of the event. Events that require expedited reporting (are grade 3 or higher or SAEs of any grade) must be reported within 2 reporting days (see guidance below) of site awareness. Grades 1 & 2 events and all community UEs must be reported within 5 reporting days of site awareness.

Reporting Days:

- A reporting day starts at 12:00 AM (midnight) and ends at 11:59 PM local time.
- A day is counted as a reporting day regardless of the time of day that awareness occurred. The day a site indicates that site personnel became aware of an EAE that meets reporting criteria shall count as day 1 if that day occurs on a reporting day (i.e., Monday through Friday). If that day occurs on a non-reporting day (i.e., Saturday or Sunday), then the next reporting day shall count as day 1.
- Monday through Friday count as reporting days.
- Saturday and Sunday are not considered reporting days.
- Any holiday that occurs on a Monday through Friday counts as a reporting day.

10.0 STATISTICAL/ANALYTIC CONSIDERATIONS

10.1 Study Design

This protocol uses three distinct phases, each with its own study design. Phase I will consist of qualitative research using focus groups of both: (1) the study population (i.e., YMSM and YTW); and (2) employers of the study population. The goal of Phase I is to tailor the intervention, designed to increase employment in an adult population, to the study population.

Phase II and III of the protocol will use a pre-/post design to determine preliminary efficacy of the revised intervention tailored to youth and designed to increase employment. Additional secondary outcomes, and potential mediators and effect modifiers of the intervention, will be considered.

10.2 Sample Size and Power Estimates

Given the exploratory nature of this study and limited access to this population, a power calculation was not performed. A repeated measures design was chosen to reduce the variability in the estimate of the treatment effect, at the expense of having a comparison group. This trade-off was appropriate given the exploratory nature of a pilot study and the limited access to the study population.

10.3 Statistical Analysis Plan

10.3.1 Data Analysis

The analytic plan is designed to: (1) tailor the adult intervention to youth; (2) assess intervention feasibility, acceptability, and satisfaction; and (3) determine preliminary efficacy of the intervention by comparing pre-/post assessments of employment and sexual risk behaviors.

<u>Phase I</u>

Data collection, storage, and analysis will take place at the study site (University of Chicago) and will be the responsibility of the Protocol Chair.

Interviews and focus groups will be transcribed and coded by trained qualitative researchers. These transcripts will be coded for patterns and themes that emerge from the data, and these data will be used to inform the revision of the employment intervention that will then be pilot-tested. All focus groups and

key informant interviews will be digitally audio-recorded, transcribed (verbatim), and analyzed using emergent inductive logic data aggregation and analysis in Atlas.ti 7.0. Major emergent themes will be used to create a codebook and two-independent coders will analyze all data separately and compare coding schema for internal reliability (Kappa) (Aim 1). Descriptive statistics will be used to analyze the proportions and central tendencies for all feasibility, acceptability, and satisfaction measures: helpfulness, comprehensibility, quality, content appropriateness, engagement, utility, satisfaction, belief in efficacy, and recommendation to a friend.

Datasets for Phase I will be cleaned, verified and archived, and then entered into SPSS for analyses. All database files will be password-protected and backed up to a secure university server daily.

Phase II and III

10.3.1.1 Descriptive statistics

Descriptive statistics will be used to analyze the proportions and central tendencies for participant sociodemographic characteristics collected in the surveys completed by participants in the pilot-tests. We will first generate frequencies, means, and other measures of central tendency as appropriate to describe our sample and outcomes at each of the three time points (T1, T2, T3). Sensitivity analyses will be performed to address extreme outlying variables, including the removal of records with extreme outlying values from analyses.

Changes in primary and secondary outcomes between Baseline (T1) and Follow-Up (T3) will be assessed using paired t-tests for continuous variables and McNemar's test for categorical variables. Other statistical tests that appropriately account for the correlation in the dataset will be considered as needed. All hypothesis testing will be done at an alpha-level of 0.1, given the pilot/exploratory nature of the study.

10.3.1.2 Modeling

The primary goal of the modeling will be to help evaluate what characteristics could be mediators or effect modifiers of the effect of the intervention. Continuous outcomes will be analyzed using linear regression or generalized linear models, discrete outcomes will be analyzed using Poisson regression, and logistic regression will be used for binary and categorical outcomes. Only variables that have a statistically significant univariate relationship with the given outcome, at an alpha-level of 0.2, will be considered as potential mediators or effect modifiers for the effect of the intervention.

Datasets for Phase 2 and 3 will be collected using CDART and cleaned, verified and archived by the ATN CC.

10.4 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 can complicate the statistical analyses and/or result 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 multiple imputation will be used.

When the primary endpoint is missing, one data analysis will be conducted using only cases with the endpoint.

Participants who do not complete all of the workshops will still be included in the analysis if they attend the follow up visit (T3), in a similar manner as intent-to-treat, where individuals are assumed to have received the intervention that was intended. We will also conduct a sensitivity analysis excluding these

participants, in an attempt to understand their potential impact on the preliminary estimates of intervention efficacy.

11.0 HUMAN SUBJECTS

This study will be conducted in compliance with the protocol, ICH Good Clinical Practice guidelines, and 45 CFR Part 46.

11.1 Participant Confidentiality

All laboratory specimens, ACASI visit surveys, evaluation forms, and other research-related records will be identified by SID only to maintain participant confidentiality. Only contact information approved by the study participant will appear on any study contact forms and reports, and these will be securely maintained by both the site and the CC. All records with personally-identifying information will be maintained under double locks at the study site, with access limited to designated site research personnel. Any study records that need to be transported between community sites and the study site will be securely maintained in locked boxes and transported only by authorized personnel listed in a Note to File.

Any laboratories used to test biological specimens will not have any study-specific identification recorded on their labels or associated requisition forms. Study data will not be released without written permission of the participant (and parent or legal guardian, when applicable), except as mandated by the law.

Once all data has been collected, identifying participant information (including name) will be stripped from the database. Consents will only be accessible to designated research staff, and stored in a locked filing cabinet in secure offices.

Computer files consisting of the participant tracking database, study data files, and transcriptions will be stored on a UNC server. The participant tracking database contains contact information and is used to schedule and track study visits, and is completely password protected. The tracking database does not contain any clinical (i.e., personal health information) or research-based information; it only has information the participant has agreed to provide for the purposes of tracking and communication.

Data files are exported from the web-based ACASI program (administered on a web-based iPad platform) to a UNC server and imported into the CDART database for storage and analysis. Transcripts are entered into Atlas.ti for storage and analysis also on the UNC server. Data files do not include information that could be used to identify the participant from the data file alone. CDART is protected with industry recognized security standards which will encrypt data and will be further protected by login credentials for limited access, to protect participant confidentiality.

11.1.1 Record Retention

All data will be destroyed 7 years after the study is completed or per NIH and/or institutional guidelines, whichever is more conservative. Identifiers will be stripped from any study databases or logs at the completion of the study.

11.2 Certificate of Confidentiality

To further protect the privacy of the study participants, the ATN has obtained a Certificate of Confidentiality from the U.S. Department of Health and Human Services (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 (Appendix V).

11.3 Risks and Benefits

11.3.1 Risks

Participants in this study are exposed to few risks. The primary risks are loss of confidentiality and potential discomfort or embarrassment in discussing some of the sensitive and personal topics probed in the interviews, focus groups, and surveys. Data and safety monitoring will be performed by the trained data collectors and research team to assure that data are entered completely and participant confidentiality is maintained. If necessary, research staff will complete an Untoward Event report and immediately inform the Principal Investigator, so that s/he can ensure accurate reporting to the IRB. Finally, the Principal Investigator will include a summary of all Untoward Events as part of continuing IRB review.

Risks to participants in this research study may include:

Risk Category: Research not involving greater than minimal risk (45 CRF §46.404 and 21 CFR §50.51)

Participation in this study poses no more harm or discomfort 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 emotional discomfort or distress due to the personal nature of some 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 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

Information from this study may benefit other youth, now or in the future, by understanding methods to motivate HIV-positive young people to start and adhere to their prescribed HIV treatments.

11.4 Institutional Review Board (IRB) 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 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.

11.4.1 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

Participating site IRBs will be requested to grant a waiver of parental/legal guardian consent to participate in this research study for youth participants under the age of legal majority based on state or local laws.

Under 45 CFR Part 46.4116 (c), an IRB has the authority to waive parental permission if it determines that "a research protocol is designed for conditions or 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 research subjects 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 supply specimens for routine HIV monitoring. 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 site 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.
- 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.

Under Illinois law (410 ILCS 305/9) minors can consent to STI and HIV testing without the consent or knowledge of said minor's parent.

11.6 45 CFR Parts 160 and 164 Standards for Privacy of Individually Identifiable Health Information ("Privacy Rule" Pursuant to the Health Insurance Portability and Accountability Act - HIPAA)

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

11.7 Study Discontinuation

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

12.0 PUBLICATION OF RESEARCH FINDINGS

NICHD and ATN policies will govern publication of the results of this study. Publication of the results of this trial will be governed by the ATN Publications Policy, which will be established by the Publications Committee. Any presentation, abstract or manuscript will be made available for review by the Publications Committee prior to submission.

13.0 BIOHAZARD CONTAINMENT

As the transmission of HIV and other blood borne pathogens can occur through contact with contaminated needles, blood, and blood products, appropriate blood and secretion precautions will be employed by all personnel in the drawing of blood and shipping and handling of all specimens for this study, as currently recommended by the Centers for Disease Control and Prevention. These procedures can be found at www.cdc.gov.

ATN specimens will be transported in accordance with Federal and local laws, and in compliance with OSHA blood-borne pathogens standards as applicable. This policy includes the samples being transported by ground to the local laboratory. Compliance will be achieved by education of personnel involved with packaging and transporting specimens.

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APPENDIX I

Schedule of Evaluations

Study Component		Pre-Pilot	Pre-Screening	T1: Baseline	T2: Immediate Post-Intervention	T3: 8 Month Follow-Up
Formative Research						
	Focus Group Interviews	X				
	Key Informant Interviews	X				
	Community Advisory Board	X	X	X	X	X
	Pre-Test	X	X	X	X	
Intervention Pilot Test						
	Time Window				0-2 weeks post-intervention	± 4 weeks 8 months post-intervention
	Pre-Screening Survey		X			
	Informed Consent			X		
	Eligibility Survey			X		
	ACASI: Sociodemographics, employment variables, HIV risk behavior, and potential effect modifiers		X	X		X
	Biospecimen: HIV/STI screening and drug testing			X		X
	ACASI: Feasibility, acceptability, and satisfaction of intervention, employment variables, HIV risk behavior				X	
	Untoward Events Assessment	X	X	X	X	X

APPENDIX II

Phase I Documents

Focus Group Guide

Work2Prevent Focus Group Guide

Hi everyone. Thanks for volunteering to talk with us. My name is X and this is X. X will be assisting me and taking notes during our group.

There are no right or wrong answers. We just want to hear about your thoughts and experience. You may feel the same or differently than others in the group. This is okay. If you want to follow up on what someone has said, you want to agree, disagree, or give an example, feel free to do that. You can direct your comments to others in the group to respond. We just ask that only one person speaks at a time.

I am here to ask questions, listen, and make sure everyone has a chance to share. We would like to hear from all of you so if you're talking a lot, I may ask you to give others a chance. If you aren't saying much, I might call on you to share your ideas. We will be recording the session to make sure we don't miss anything you say, but what you say will not be linked to your name in the course of our research.

Also, we want to remind you to please not share what you hear in this group today. By nature, a focus group is neither private nor confidential. However, it is important that what we say here stays within the group. If you want to use the bathroom, please feel free, we just ask that you get up quietly. Please keep your cell phones turned off until we finish the session. We really appreciate your full participation.

Let's begin. To find out a bit more about each other, we will go around the circle. When it is your turn, please tell us your first name, your favorite city (other than Chicago), and where you'd like to go on vacation if you could go anywhere in the world.

1. I'd like to start by talking about employment in general. What kinds of jobs have you had in your lifetime? What is your favorite job that you have had? What did you like about that job? What is your least favorite job? What did you not like about that job?

2. Let's talk about the job search. How do you find out about jobs you might want to apply for? [Probe: internet – what sites in particular?, friends, family, etc.] When looking online, what do you search for? When you look at a job posting, what makes you decide to apply? What makes you decide not to?

3. Now let's talk about applying for a job. What kinds of things have you had to do to apply for a job? [Probe: in person vs. online application] Have you had to provide a resume? How did you get your resume ready? What do you include on your resume? What do you leave off?

4. Okay, let's say you get an interview for a job. How do you prepare for the interview? What do you wear? What time do you show up? How does your self-presentation during an interview differ from your self-presentation on a regular day?

5. What kinds of experiences have you had during job interviews? What questions have you been asked? What was the hardest question to answer? Have you been asked things that seemed inappropriate (unprofessional)? Can you give examples? Have you ever not gotten a job because of your sexual orientation or gender identity? How do you know that was the reason?

6. So let's say you get hired for a job (congratulations!). What kinds of challenges might a young (gay man OR trans woman) of color face when starting a new job? When if ever do you disclose your (sexual orientation OR gender identity)? [Transwomen: How do you deal with providing paperwork that might not match your gender presentation?]

7. Thinking about discrimination at work now: Have you ever had to interact with a (homophobic/transphobic) co-worker or boss? What happened? How did you respond? Were there any people at that job who supported you? Were there any policies against discrimination?

8. What is the longest you have ever worked at the same place? What was it about that job that made you want to stay? Did your employer have policies that kept other co-workers or supervisors from discriminating against you because of your sexual orientation or gender identity? What were those policies? How were they communicated to employees? How were they enforced?

9. Thinking about positive work environments now: Have you ever had a job where you felt safe being "out" about your sexual orientation/gender identity? What made that environment feel safe and supportive? What could employers promote that kind of supportive environment?

Thank you so much for your time and input! We really appreciate your participation, and we value your feedback.

Key Informant Employers Guide

Key Informant Interviews: LGBT-inclusive employers

Thank you for agreeing to participate in this interview. We are hoping to gather important information in order to better understand the experiences of hiring managers in supporting diversity in hiring, specifically among LGBT individuals. We appreciate your time and are very interested in your point of view and opinion.

We would greatly appreciate it if you could please turn off your cell phone during the session.

Before we start, I would like to remind you that there are no right or wrong answers to the questions as we talk. We are holding this interview because we want to learn about your experiences and to hear from you*. Any information shared in this session will be confidential. Any information you share will be de-identified to protect the anonymity of you and your employer. You do not have to answer any questions you do not wish to answer. If you need to take a break at any point, please let me know.*

1. Please tell me about your position at X company
    a. How long have you worked at X company?
    b. How long have you been in your current position?
    c. What is your role in the hiring process?
    d. How many people have you been involved in hiring?

2. What you typically look for in an employee? (May need to specify type/level of employee)
    a. Probes: specific skills, disposition/personality, experience, work ethic, diversity
    b. Can you give me an example of a recent hire? What was the position you were hiring for? What were you looking for in that employee? How did you determine that the person you hired was the right person for the job?

3. Now thinking a bit more specifically about LGBT people - can you tell me about any protocols or policies you have to recruit, hire, and retain individuals who identify as LGBT, that is lesbian, gay, bisexual or transgender? (probe: Lesbian, Gay, Bisexual, Transgender)

    a. Probe: Are your policies the same for all of those groups, or are there different policies for sexual orientation and gender identity? Can you explain the reasoning behind that? How does that work in practice?
    b. Probe: Let's talk specifically about recruiting employees here: what policies do you have to recruit LGBT employees? How successful have these policies been? What do you think could be done to improve these policies?
    c. Probe: What about policies to retain LGBT employees? How successful have these policies been? What do you think could be done to improve these policies?

4. What are some challenges that someone who is LGB might face working in this field?
    a. What about challenges someone who is LGB might face working at this organization/company specifically?
    b. How do the higher-ups at your company address these challenges?
    c. How do the other staff at your company address these challenges?
    d. Can you give an example of this from your own company?

5. What are some challenges that someone who is transgender might face working in this field?

   a. What about challenges someone who is transgender might face working at this organization/company specifically?
   b. How do the higher-ups at your company address these challenges?
   c. How do the other staff at your company address these challenges?
   d. Can you give an example of this from your own company?

6. What are some benefits to the company from having LGBT employees?
   a. Can you give an example of how an LGBT individual has added value to your company?

7. How do your clientele factor into your company's policies and practices regarding certain sexual and gender minorities? (probe: Lesbian, Gay, Bisexual, Transgender)

8. How might other employees and key stakeholders (board members, shareholders, funders, etc) factor into your company's policies and practices regarding certain sexual and gender minorities?

9. What barriers to hiring and retaining young transwomen of color in particular have you experienced? (Probe: job readiness, interview performance, stereotypes of other employees, self-presentation, personality/disposition, etc.)

10. What barriers to hiring and retaining young gay or bisexual men color in particular have you experienced? (Probe: job readiness, interview performance, stereotypes of other employees, self-presentation, personality/disposition, etc.)

Informant YMSM and YTW Guide

Work2Prevent IDI Guide for MSM/TW

Hi there, my name is _____. Thanks for volunteering to talk with me today. Before we get started on the interview, I'd just like to remind you of a few things. First, there are no right or wrong answers. I just want to hear about your thoughts and experience. Second, I'll be recording the interview today so that I can focus on the interview instead of taking notes. The recording will only be used for our research, and your answers will be confidential, meaning that your name will never be used in connection with reports from this study. Third, you may skip any question you do not want to answer, and you may end the interview at any time. If you need a break at any point, just let me know. Finally, I ask that you keep your cell phone on silent or turned off until we finish the interview. I really appreciate your full participation. Do you have any questions for me at this point? Feel free to ask at any point if something comes up. Okay, let's get started!

1. I'd like to start by talking about your employment history. Please walk me through all of the jobs you've had, starting with your very first paid employment.

    a. What was your first job? How old were you when you got it? How long did you work there? What kinds of things did you do?

    b. What was your next job? [Repeat questions for each job until present time.]

    c. What was your favorite job that you have had? What did you like about that job? What was your least favorite job? What did you not like about that job?

2. Now let's talk about the job search. How do you find out about jobs you might want to apply for? How did you find out about the last job you had? [Probe: internet – what sites?, friends, family, etc.]

    a. When looking online, what do you search for? When you look at a job posting, what makes you decide to apply? [Probe: skills, experience, job type, location, compensation, etc.] What makes you decide not to?

    b. When you hear about a job from family or friends, what sorts of things do you ask? [Probe: skills, experience, job type, location, compensation, etc.] What makes you more likely to apply for a job that someone tells you about? What makes you less likely to apply?

    c. When you see a help wanted ad or sign, how do you decide whether to apply for the job advertised? [Probe: skills, experience, job type, location, compensation, etc.]

    d. Have you figured out any ways to tell if an employer is LGBT friendly? If yes, how did you figure this out? Have you been able to apply this when looking for jobs? If not, are there things that employers could do that would help you know that they are LGBT friendly?

3. Now let's talk about applying for a job. What kinds of things have you had to do to apply for a job? [Probe: in person vs. online application] [Probe: Think about the last job you applied for…]

   a. Have you had to provide a resume? How did you get your resume ready? What do you include on your resume? What do you leave off? When did you first create a resume? How often have you revised or rewrote it?

4. Okay, let's say you get an interview for a job. How do you prepare for the interview?

   a. What do you wear? How does your self-presentation during an interview differ from your self-presentation on a regular day?

   b. What time do you show up? How do you act?

5. Think specifically about the last job you applied for: did you interview for that? What happened during the interview? What questions did the interviewer ask?

   a. How did that interview compare to other job interviews you've had? What kinds of experiences have you had during job interviews?

   b. What questions have you been asked? What was the hardest question to answer? Have you been asked things that seemed inappropriate (unprofessional)? Can you give examples?

   c. Have you ever not gotten a job because of your sexual orientation or gender identity? What made you think that was the reason?

6. So now let's talk about what happens when you start a new job. What kinds of challenges have you faced as a young (gay man OR trans woman) of color when starting a new job?

   a. When (if ever) have you disclosed your (sexual orientation OR gender identity) to your co-workers? What about to your boss?

   b. [Transwomen: How do you deal with providing paperwork that might not match your gender presentation?]

7. Thinking about discrimination at work now: Have you ever had to interact with a (homophobic/transphobic) co-worker or boss? Can you tell me about that experience?

   a. What happened? How did you respond?

   b. Were there any people at that job who supported you? What did they do?

   c. Were there any policies against discrimination at your job? What were those policies? How were they enforced, if at all?

8. What is the longest you have ever worked at the same place?

   a. What was your job? What was it about that job that made you want to stay?

   b. Did your employer have policies that kept other co-workers or supervisors from discriminating against you because of your sexual orientation or gender identity? What were those policies?

c. How were they communicated to employees?

d. How were they enforced?

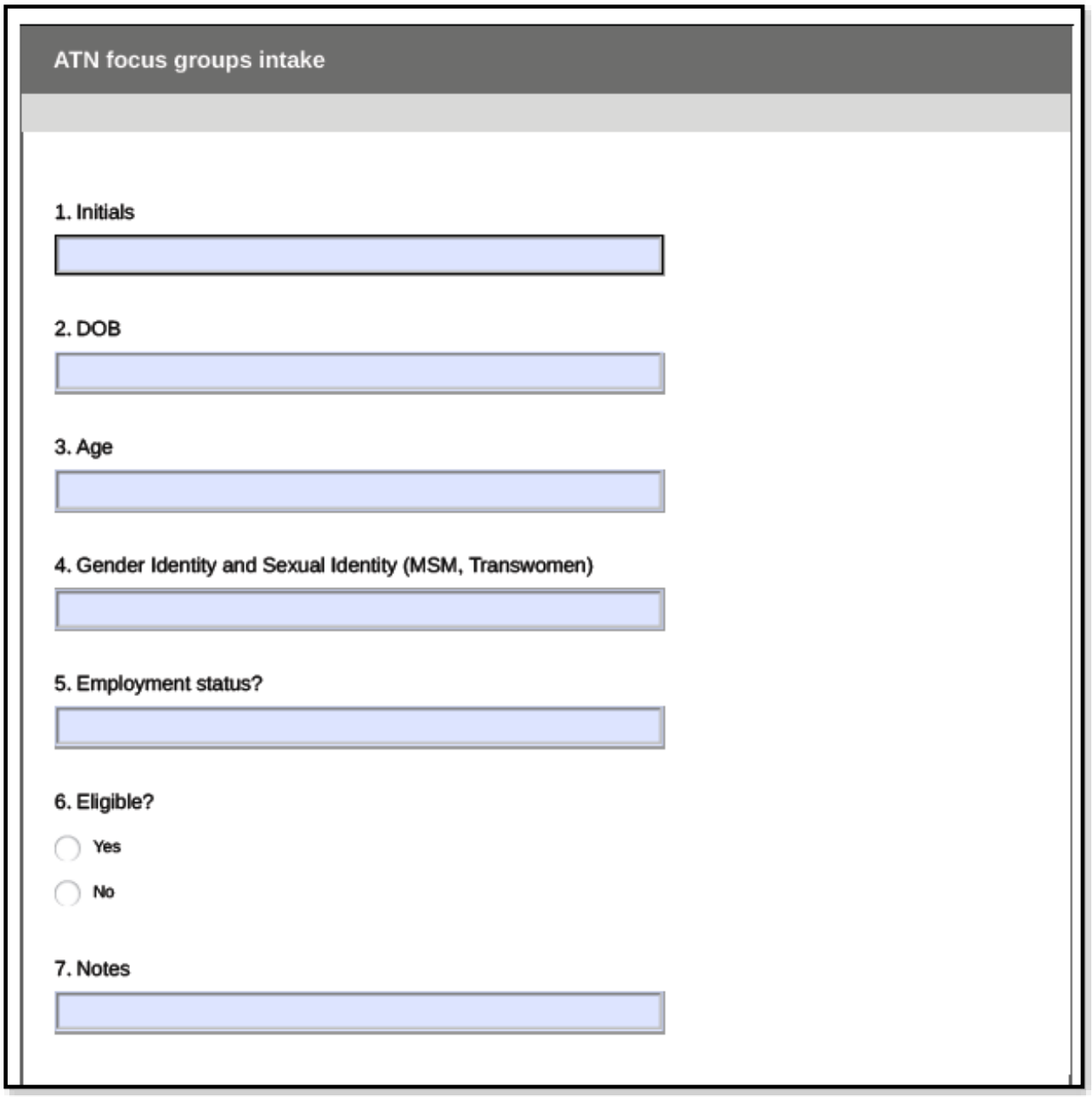
9. Thinking about positive work environments now: Have you ever had a job where you felt safe being "out" about your sexual orientation/gender identity?

   a. What made that environment feel safe and supportive?

   b. How could more employers promote that kind of supportive environment?

Thank you so much for your time and input! I really appreciate your participation, and I value your feedback.

Screening Instrument



ATN focus groups intake

1. Initials

2. DOB

3. Age

4. Gender Identity and Sexual Identity (MSM, Transwomen)

5. Employment status?

6. Eligible?

- Yes
- No

7. Notes

APPENDIX III

Planned Enrollment Report – Pilot Test

This report format should NOT be used for collecting data from study participants.

Study Title: Work-to-Prevent: Employment as HIV prevention for young men who have sex with men (YMSM) and young transgender women (YTW) [Pilot Test (n=70)]

Domestic/Foreign: Domestic

Comments: We define male to include anyone who was assigned male at birth, which would include young transgender women (YTW)

Racial Categories	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		Total
	Female	Male	Female	Male	
American Indian/ Alaska Native	0	0	0	0	**0**
Asian	0	0	0	0	**0**
Native Hawaiian or Other Pacific Islander	0	0	0	0	**0**
Black or African American	0	48	0	4	**52**
White	0	0	0	12	**12**
More Than One Race	0	4	0	2	**6**
Total	**0**	**52**	**0**	**18**	**70**

APPENDIX IV

iFOUR Description

Description of the iFOUR Program

The Increase Individual Income and Independence program (iFOUR) is an employment program that was developed over ten years ago to target the employment needs of HIV-positive people. The program was based on the Supported Employment framework that was developed to help connect people with a range of disabilities (physical and cognitive) to employment because of the benefits of employment, both monetary and non-monetary. Thus, researchers at the University of Illinois-Chicago collaborated with Chicago House, a housing and support organization for HIV-positive individuals, to develop a Supported Employment program for HIV-positive individuals. Like Supported Employment, iFOUR provides a variety of supports to aid in participants' job success, such as job training referrals, client-tailored job placement, post-employment assistance, and benefits planning. The program includes regular interviews to evaluate program outcomes, such as medication adherence, use of drugs and alcohol, and assessments of physical and mental health. Since 2005, the iFOUR program has been refined to better tailor to the needs of HIV-positive individuals, including the addition of one-on-one work with a career specialist. These specialists assess job readiness and are trained in the impact of HIV/AIDS on employment, so as to best assist participants with their career aspirations. They also assist with linking participants to additional educational resources and provide support with interview preparation and development of resumes and cover letters. iFOUR also includes a four-week training workshop that is tailored to the needs of HIV-positive participants, dealing with questions such as workplace discrimination, benefits maintenance, and the relationship of health beliefs and work. The workshop also covers confidence and communication skills, while highlighting the non-monetary benefits of employment. The iFOUR program has had positive outcomes for participants, documented in several studies (see references below). The goal of the current study is to tailor and then pilot test the iFOUR program for individuals who are HIV-negative but at high-risk for acquiring HIV.

Related References

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APPENDIX V

Certificate of Confidentiality

NIH Eunice Kennedy Shriver National Institute of Child Health and Human Development
Health Research Throughout the Lifespan

6710B ROCKLEDGE DRIVE
Rm 2158
Bethesda, MD 20817

12/21/2016

Dr. Myra Carpenter
University of North Carolina at Chapel Hill
104 Airport Drive, CB 1350
Suite 2200
Chapel Hill, NC 27599

Dear Dr. Carpenter,

Enclosed is the AMENDED Confidentiality Certificate, protecting the identity of research subjects in the project entitled "The Adolescent Medicine Trials for HIV/AIDS Interventions Network (ATN). Please be sure that the consent form given to research participants accurately states the intended uses of personally identifiable information and the confidentiality protections, including the protection provided by the Certificate of Confidentiality with its limits and exceptions.

This amendment reflects addition of the following new Contact PI as well as new Principal Investigators/research projects:

Contact PI: Myra Carpenter, Ph.D., Michael Hudgens, Ph.D., University of North Carolina, Chapel Hill (Adolescent Medicine Trials Network for HIV/AIDS Interventions Coordinating Center)

- Lisa Hightow-Weidman, M.D., University of North Carolina, Chapel Hill; Patrick Sullivan, M.D., Emory University, Atlanta, GA (The UNC/Emory Center for Innovative Technology (iTech) across the prevention and care continuum)
- Sylvie Naar-King, Ph.D., Wayne State University, Detroit; Bonita Stanton, Ph.D., Seton Hall University, South Orange, NJ; Jeffrey Parsons, Ph.D., Hunter College, New York, NY (Scale it Up: Effectiveness-implementation research to enhance HIV-related self-management among youth)
- Mary Jane Rotheram-Borus, Ph.D., University of California, Los Angeles (A Comprehensive community-based strategy to optimize the HIV prevention and treatment continuum for youth at HIV risk, acutely infected and with established HIV infection)

If you determine that the research project will not be completed by the expiration date, **12/31/2021**, you must submit a written request for an extension of the Certificate three (3) months prior to the expiration date. If you make any changes to the protocol for this study, you should contact me regarding modification of this Certificate. Any requests for modifications of this Certificate must include the reason for the request, documentation of the most recent IRB approval, and the expected date for completion of the research project.

Please advise me of any situation in which the certificate is employed to resist disclosure of information in legal proceedings. Should attorneys for the project wish to discuss the use of the certificate, they may contact the Office of the NIH Legal Advisor, National Institutes of Health, at (301) 496-6043.

Correspondence should be sent to:

Dennis Twombly Ph.D.
Eunice Kennedy Shriver National Institute of Child Health and Human Development

Sincerely,

Approved Date: 12/21/2016

Dennis Twombly Ph.D.
Deputy Director OEP
Eunice Kennedy Shriver National Institute of Child Health and Human Development

CONFIDENTIALITY CERTIFICATE

CC-HD-11-60E2

issued to

University of North Carolina at Chapel Hill

conducting research known as

The Adolescent Medicine Trials for HIV/AIDS Interventions Network (ATN).
This certificate amends the certificate numbered CC-HD-11-60E1 issued on 07/10/2015

In accordance with the provisions of section 301(d) of the Public Health Service Act 42 U.S.C. 241(d), this Certificate is issued in response to the request of the Principal Investigator, Dr. Myra Carpenter, to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Carpenter is primarily responsible for the coordination and conduct of this research for the ATN, which is funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD-NIH).

This amendment reflects addition of the following new Contact PIs as well as new Principal Investigators/research projects:

Contact PIs: Myra Carpenter, Ph.D., Michael Hudgens, Ph.D., University of North Carolina, Chapel Hill (Adolescent Medicine Trials Network for HIV/AIDS Interventions Coordinating Center)

- Lisa Hightow-Weidman, M.D., University of North Carolina, Chapel Hill; Patrick Sullivan, M.D., Emory University, Atlanta, GA (Project: The UNC/Emory Center for Innovative Technology (iTech) across the prevention and care continuum)
- Sylvie Naar-King, Ph.D., Wayne State University, Detroit; Bonita Stanton, Ph.D., Seton Hall University, South Orange, NJ; Jeffrey Parsons, Ph.D., Hunter College, New York, NY (Project: Scale it Up: Effectiveness-implementation research to enhance HIV-related self-management among youth)
- Mary Jane Rotheram-Borus, Ph.D., University of California, Los Angeles (Project: A Comprehensive community-based strategy to optimize the HIV prevention and treatment continuum for youth at HIV risk, acutely infected and with established HIV infection)

Under the authority vested in the Secretary of Health and Human Services by section 301(d), all persons who:

1. are enrolled in, employed by, or associated with any of the below named universities and their contractors or cooperating agencies,

    - University of North Carolina, Chapel Hill NC
    - Emory University, Atlanta GA
    - Wayne State University, Detroit MI
    - Hunter College, NYC NY
    - University of California, Los Angeles CA

2. and have in the course of their employment or association access to information that would identify individuals, who are the subjects of the research, pertaining to the project known as *The Adolescent Medicine Trials for HIV/AIDS Interventions Network (ATN)*

are hereby authorized to protect the privacy of the individuals, who are the subjects of that research, by withholding their names and other identifying characteristics from all persons not connected with the conduct of that research.

The primary mission of the Adolescent Trials Network is to conduct research, both independently and in collaboration, with existing research networks and institutions, to explore promising behavioral, microbicidal, prophylactic, therapeutic, and vaccine modalities in HIV-infected and HIV at-risk adolescents, age 12 through 24. ATN collaborative activities are administered by the PD(s)/PI(s) at participating sites, supporting staff, the Executive Committee, the Coordinating Center, and NIH collaborating staff. Research Projects funded and developed by the ATN are all subject to appropriate IRB review and approval.

All ATN collaborative activities are covered under this Certificate of Confidentiality, including enrollments into ATN protocols registered at any of the subject recruitment venues collaborating with and/or contracted by any of the 4 principal investigators and their affiliated institutions. A listing of the subject recruitment venues and numerous protocols are on file with the application along with the new names and leadership re-organization.

A Certificate of Confidentiality is needed because sensitive information will be collected during the course of the study. The certificate will help researchers avoid involuntary disclosure that could expose subjects or their families to adverse economic, legal, psychological and social consequences.

All subjects will be assigned a code number and identifying information and records will be kept in locked files in a secure and confidential location at the institution. The study staff for every research project must keep information on everyone in a study private.

This research is currently underway and is expected to end 12/31/2021.

As provided in section 301 (d) of the Public Health Service Act 42 U.S.C. 241(d):

"Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

This Certificate does not protect you from being compelled to make disclosures that: (1) have been consented to in writing by the research subject or the subject's legally authorized representative; (2) are required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or regulations issued under that Act; or (3) have been requested from a research project funded by NIH or DHHS by authorized representatives of those agencies for the purpose of audit or program review.

This Certificate does not represent an endorsement of the research project by the Department of Health and Human Services. This Certificate is now in effect and will expire on **12/31/2021**. The protection afforded by this Confidentiality Certificate is permanent with respect to any individual who participates as a research subject (i.e., about whom the investigator maintains identifying information) during the time the Certificate is in effect.

Sincerely,

Signed Date:

Della Hann Ph.D.
Associate Director for Extramural Research
Eunice Kennedy Shriver National Institute of Child Health and Human Development