ADOLESCENT MEDICINE TRIALS NETWORK FOR HIV/AIDS INTERVENTIONS
U19HD089875

Consent and Assent
Comparative effectiveness trial of a clinic-based delivery of the Young Men's Health Project (YMHP) targeting HIV risk reduction and substance use among young men who have sex with men (YMSM)

ATN *Scale It Up* U19: 145 YMHP

ClinicalTrials.gov NCT03577301

Sponsors: National Institute of Child Health and Human Development; National Institute on Drug Abuse

11/3/2020

FLORIDA STATE UNIVERSITY

CONSENT/ASSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Comparative effectiveness trial of clinic-based delivery of an HIV risk reduction intervention (YMHP) for YMSM

Principal Investigator:

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Introduction

You are invited to be in a research study of an HIV- risk reduction program called the Young Men's Health Project (YMHP). Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone on the research team.

Key Information about the research study

Things you should know:

- The purpose of this study is to deliver and test an HIV risk reduction program among HIV-negative young men who have sex with men (YMSM). If you choose to participate, you will be asked to complete 5 surveys, 4 sessions of YMHP with a trained community health worker, and return to us for HIV and STI testing 2 times.
- Due to COVID-19, participants have the option to complete this research study in-office face to face, in-office virtually in separate assessment rooms, virtually from home with STI testing in-office, or virtual from home with STI testing at home.
- Risks or discomforts from this research include feeling uncomfortable discussing topics including HIV and sexual behavior or substance use as well as feeling minor pain from the HIV and STI tests.
- The study will help to develop a program to reduce the risk of exposure to HIV among young men who sex with men.

Study Title: Comparative effectiveness trial of clinic-based delivery of an HIV risk reduction intervention (YMHP) for YMSM

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- Taking part in this research project is voluntary. You don't have to participate and can stop at any time.

Please take the time to read this entire form and ask questions before deciding whether to take part in this research project.

Why is this study being done?

This study is being conducted by Angulique Outlaw, Ph.D. at Wayne State University and Tyrel Starks, Ph.D. at Hunter College, The City University of New York (CUNY). It is funded by The National Institute of Health (NIH).

The purpose of this study is to deliver and test an HIV risk reduction program among HIV-negative young men who have sex with men (YMSM). This program, called the Young Men's Health Project (YMHP), is a program focused on reducing the risk of getting HIV that has already shown to be effective in research settings. This research project will explore how this program works in "real world" clinics, and will compare the program being delivered two different ways: in person (at clinic) or remotely (over the phone, by video chat such as Skype or FaceTime).

Why are you being asked to take part in this study?

You were selected as a possible participant in the YMHP because you have identified as an HIV-negative young man who has sex with other men, have used drugs or alcohol previously, and are between the ages of 15 and 24. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

How many people are expected to take part in this study?

We will enroll 180 participants in total across three sites. In addition to enrolling 60 participants at Wayne State University we will enroll 60 participants at both University of Miami and Children's Hospital of Philadelphia.

Study procedures

If you agree to be in the study, you will participate in the YMHP program in person or remotely depending on the preference of you or the study team and which group you are randomly assigned to for participation (like flipping a coin). You will be part of a group of 180 participants who are taking part in the program at three sites nationally.

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If you agree to take part in this study, you will complete the following activities:

(1) **Baseline (first) visit**: After providing your consent to participate either in person or virtually, you will complete a confidential computer-based survey that will ask about your drug and alcohol use, sexual behavior and general thoughts and feelings. This will take about 45 minutes to complete. If eligible to continue you will participate in STI testing (testing for sexually transmitted infections) and take a confidential urine drug test. STI testing will consist of a urine sample an anal self-swab of your rectal mucosa and a finger prick or a blood draw may be performed for syphilis testing. This testing may be done in office or at home. If you elect to do testing at home, the study team or Molecular Labs will send you a testing kit to the address you specify. It will contain an Oraquick HIV test, supplies to collect urine and rectal swab for ST Testing, and a Dried Blood Spot Card for Syphilis testing. At this visit you will also complete Session 1 of the YMHP program. This session will be focused on either sexual risk or substance use and will be audio recorded. The entire baseline visit may take 3-4 hours to complete. If attending the Baseline visit at the office is not possible, you may be asked to do the Baseline visit virtually over HIPAA Compliant Zoom.

(2) YMHP sessions: You will be randomized (like flipping a coin) into one of two study groups: you will either complete four sessions of YMHP counseling or receive HIV test and counseling only. If you are assigned to YMHP sessions, you will complete session 1 of the YMHP program today. This session will be focused on either sexual risk or substance use and will be audio recorded. You will then complete 3 additional YMHP sessions focused on sexual risk and substance use. The sessions can be completed in person or remotely depending on your choice or the study team's choice. Each of these sessions will be audio recorded and will take about 40-60 minutes to complete. No video will be recorded. If you are assigned to HIV testing only, you should have recently received a HIV test at this clinic. We will ensure you are referred to relevant services that you may find beneficial. You will not need to come back until the post-test assessment. You may complete 4 sessions of YMHP after your 9 month follow-up.

(3) Immediate post-test assessment: Three months after your baseline appointment you will be scheduled to complete an immediate post-test assessment. During this assessment you will complete a confidential computer-based survey about your drug and alcohol use, sexual behavior and general thoughts and feelings. This survey can be completed at the clinic or by using a survey link we send to you electronically. This survey will be similar to the baseline survey and it will take about 45 minutes to complete.

(4) Follow up assessments: There will be three additional follow up assessments for you to complete. These follow up assessments will occur in three month intervals until approximately 9 months after your post intervention assessment (i.e. 3 months, 6, months, and 9 months).

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The 3 month and 9 month follow up assessments include completing a confidential computer-based survey to be completed at home or in-office and require a confidential urine drug test, HIV and STI testing. The urine drug test, HIV and STI testing can be performed at this clinic or by using a self-test kit we or Molecular Labs will mail to your home if you choose. If you do not complete the 3 month or 9 month urine drug test, Oraquick HIV and STI testing you will be asked to complete these tests at your next assessment. If you complete Oraquick testing, we may conduct this testing with you over HIPAA Compliant Zoom.

The HIV test will test for the presence of antibodies to HIV or HIV antigens. If the result is positive for HIV, you may be referred for a confirmatory HIV test when necessary. A YMHP staff member (from clinic or Hunter College) trained in HIV testing and counseling will discuss the meaning of the test results with you, and explain the importance of timely access to health care, including antiretroviral therapy. If you test positive for an STI from a test at the clinic you will receive referrals for treatment from a trained YMHP clinic research staff member. If you test positive for an STI at home a trained member from the YMHP research staff at Hunter College or from our clinic will contact you by phone or email to inform you of these results and refer you to treatment services located near your home. Urine drug test results will be provided to you upon request.

The 6 month assessment does not require urine drug test, HIV and STI testing so therefore these assessments can be completed using an electronic link we send to you or you can complete the confidential computer-based survey at clinic if you choose. This survey will be similar to the baseline survey and it will take about 45 minutes to complete.

As part of this study you may be invited to take part in a one-on-one confidential interview with a member of our research staff to learn about your experience with participation in this research. This interview will be audio recorded. If you are invited but are not interested in participating in the one-on-one interview, you may decline and still continue in the study otherwise.

How long will I be in the study?
In total you will be in the study for approximately 12 months.

Risks of study participation
The risks and discomfort associated with participation in this study are no greater than those ordinarily encountered in daily life. The topics discussed both in the program sessions and the assessments are of a sensitive nature. Some people may feel uncomfortable talking and answering questions about topics including HIV and sexual behavior or substance use.

There is also a risk that your parents, family members or others will learn about your sexual orientation or sexual activity based on your participation in this research study. If you choose at-home HIV/STI

testing, kits may be mailed to your home address. YMHP research staff will allow your kit to be shipped to an alternate location deemed as a safe space, such as a youth center, and will require you to speak with a trained staff member to ensure these arrangements are both safe and allowable. We are excluding those aged 16 years and below from participating in at-home testing at this site, taking into account FDA age approval for OraQuick and Michigan state law on age of sexual consent.

In addition, you may experience some minor pain as a result of the swab for STI testing and finger prick for the HIV test and syphilis test. If syphilis testing is performed via a needle stick, a trained phlebotomist will perform the needle stick to minimize the risk of bruising or infection. There is a very slight risk of developing an infection at the site of the needle stick. In addition, in order to minimize potential discomfort from swabbing procedures necessary for STI testing, clinic staff will provide you with instructions on how to properly perform the swab yourself to collect specimens. Self-swabs have been routinely performed both within and outside of medical settings, therefore potential risks are no greater than those encountered during routine medical exams.

In addition to the other possible harms or discomforts related to research that we told you about, there may be risks with using web-based or online programs. First, someone may try to interfere or tamper with our collection of information from you. Second, after we collect information from you, someone may see or take information about you without permission. ~~Third, by us recording our Zoom sessions, someone outside of the study team may recognize you and know what you said or what you did as part of this study.~~ If any of these things happen, your privacy and the confidentiality of the information that you provide to us may be violated.

In addition to other possible harms or discomforts related to research that we told you about, there may be risks by having you take part in our face-to-face study activities during this time of the Coronavirus emergency. First, face-to-face activities and contact with other persons may increase the risk of getting Coronavirus. No one is yet quite sure how easily Coronavirus passes from person to person, how to know for certain when someone has or does not have Coronavirus, or what works best at preventing Coronavirus from spreading. Second, getting Coronavirus may result in a person being isolated or quarantined at home and away from work, family and other activities. Third, Coronavirus is a serious illness that may require medical care including hospital care, long-term disability, and even death.
Fourth, certain persons are at higher risk for severe illness from Coronavirus, and these persons are not permitted to take part in our study.

Persons thought to be at higher risk include:

- Being 65 years of age or older
- Prior or current exposure to persons that have Coronavirus whether or not they know it
- Persons of any age with serious medical conditions such as diabetes, and heart, lung, kidney or liver disease, or persons who are severely obese

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- Persons who have poor immunity, such as persons under cancer treatment or who have other conditions with weakened immune systems
- People who reside in nursing homes or other long-term care facilities

We will therefore be asking some questions to screen all research participants and study staff to see who may be at risk of severe illness, or who have been exposed to Coronavirus. Even after we ask these questions, if you think that at any time before or during this study you may have been exposed to Coronavirus or are at risk of severe illness, then we will ask you not to take part in this study, so please let us know.

While we will take steps to protect you from exposure to Coronavirus when you take part in our face-to-face activities, there is always the chance that you may still be exposed.

Finally, in order to reduce exposure to Coronavirus, we will ask you to stay at least six feet away from anyone else, including us, during our activities; wear a special mask to cover your mouth and nose; wear gloves to cover your hands; wear other equipment to cover your head and body; sit behind a wall or in another room nearby; wash and sanitize your hands; not to touch your face or anything else during our study activities unless we say it is OK. These steps are required. Having to do these things may not be comfortable for you and may cause you to be worried or stressed.

In addition to the risks of these Coronavirus-related harms or discomforts, this research may have risks of other Coronavirus-related harms or discomforts that are unknown at this time. If in the future we become aware of any additional harms or discomforts that may affect you, we will tell you.

Benefits of study participation
The benefits of study participation are that you may learn more about yourself, your sexual behavior, your drug and alcohol use and other thoughts, feelings and behaviors. You are also helping the YMHP research team to develop a program to reduce the risk of exposure to HIV among young men who sex with men (YMSM), which will likely benefit other members of the community.

Alternatives to study participation
There are no therapeutic alternatives available at this time. An alternative is for you not to participate in this research study. Participants always have the option not to participate in this study, and referrals to other services provided by W'SUP are available to all study participants.

Ending the study
Your participation in this study is entirely voluntary. If you decide to leave the study, please contact the Site PI to inform them of your decision. Because withdrawing data threatens the scientific integrity of the study, we plan to securely store and later use all of the previously collected data in analyses to address the

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aims of the study. It is also important to the study that we continue collecting data at the follow-up assessment. We will ask you about whether you would be willing to continue with the follow-up assessment portion of the study, but you may choose not to continue. We will also ask you about your decision to withdraw your participation in this study in order to get your feedback about ways to help improve future studies.

We may end your participation for a number of reasons:

1. During the course of the assessment it becomes clear that you do not meet study eligibility criteria,
2. Physical or psychological problems arise which would interfere with your voluntary participation in this study,
3. If we feel that it is in the best interests of your health, and/or
4. If we feel you are providing inaccurate or false information.

In addition, the research team may dismiss you if you engage in any hostile behavior toward the staff or if we find you are ineligible after completing your baseline appointment today.

Study costs/compensation

There will be no costs to you for your participation in this research study. For taking part in this research study, you will be paid for your time for both the YMHP sessions and assessment visits as follows, for a total of $275 if you complete the entire study.

Visit	Compensation amount
Baseline survey, urine drug test, STI and HIV testing and YMHP Session 1	$50 ($25 for completing the computer-based survey and $25 for completing first YMHP session and urine drug test, HIV and STI tests), plus a bus ticket for transportation or $5 if you test at home and return the testing kit.
YMHP Program Sessions 2-4	$10 for each of the three YMHP sessions ($30 total). If the baseline and three additional YMHP sessions are completed, you will receive an additional $20.
Post-test assessment	$25 computer-based survey only
3-month assessment	$50 ($25 for completing the computer-based survey and $25 for completing urine drug test, HIV and STI testing), plus a bus ticket for transportation or $5 if you test at home and return the testing kit.

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6-month assessment	$25 computer-based survey only
9-month assessment	$50 ($25 for completing the computer-based survey and $25 for completing urine drug test, HIV and STI testing), plus a bus ticket for transportation or $5 if you test at home and return the testing kit.
Qualitative Interview (optional)	$25 phone interview

You will be paid the amounts specified above via gift card.

You may refer members of your social network to participate in the study. For each person you recruit who screens eligible after the baseline visit, you will receive a $10 e-gift card incentive. You will receive this $10 incentive for up to 5 of these referrals for a maximum of $50. You will be given either a card with your unique number or a special link you can share with your friends. Study staff will know you referred that participant and compensate you accordingly.

Who can profit from study results?
No conflicts or gains have been identified in connection with this study. Florida State University reviews staff researchers for conflicts of interest.

Members of the research team working on this study may have up to $15,000 of stock in the companies that make products used in this study. This is allowed under federal rules and is not a conflict of interest.

How will my samples and data be used?
The biological specimens collected for the purposes of this study will not be used to conduct any future research and will be destroyed after analysis is completed. Your survey responses will be used to help the YMHP research team to develop a program to reduce the risk of exposure to HIV among young men who sex with men (YMSM), which will likely benefit other members of the community.

Confidentiality
Every effort will be made to keep all of the material related to you private and confidential. You will be assigned a code number, and all study related data and any other materials that may be generated by participation will be identified only by that code number. Any materials that match a code number to your name will be kept in a separate, locked file located at our clinic office and Hunter College. Your identity will be kept confidential in any presentation or publication of the results of this study. Data that cannot be linked to you individually (i.e., de-identified) will be analyzed by members of the research team and will

be kept indefinitely; these data will be saved for future use and may be shared with other researchers. By participating in this study, you are agreeing to allow us to save and share your data anonymously.

However, research information that identifies you may be shared with the FSU Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of the National Institutes of Health (NIH) and the Office for Human Research Protections (OHRP).

You will be asked to provide contact information which will help the YMHP researchers at our clinic office and at Hunter College reach you to complete follow up assessments. This information includes your name, address, telephone number, email address and other facts that could identify you. The contact information will be kept separate from your research records. The YMHP researchers at Hunter College may use this information to send you links to the surveys, send a reminder about upcoming visits or contact you to complete this research, for example if you relocate or don't have access to a clinic. This information will be stored in a secure database at Hunter College.

Additionally, if you test positive with HIV or an STI, you should understand that Michigan state laws require healthcare providers and clinical laboratories to report the test results with your personally identifying information to the local health department. The study team is required to follow these laws.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

In addition to the steps we are taking to protect your privacy and confidentiality overall, we will also take other steps to keep people from tampering with our web-based or online activities or taking information without your permission.

First, we only use web-based and online programs that follow the laws and best standards for protecting against tampering or unauthorized access. Second, we limit who may have access to our HIPAA Compliant Zoom account to only persons like you who are invited to take part and to members of the study team. Once the Zoom session is closed to taking part, no one else besides the study team has access.

Despite taking all these steps to protect your privacy and the confidentiality of your identifiable information, we are not able to guarantee that people will be unable to tamper with our web-based or online activities or take information without your permission.

Certificate of Confidentiality

Study Title: Comparative effectiveness trial of clinic-based delivery of an HIV risk reduction intervention (YMHP) for YMSM

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To help protect your privacy, a Certificate of Confidentiality has been obtained from NIH to help others from learning about your participation in this study. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena.

You should also know that there are several circumstances in which the Certificate does not provide coverage. These include when information:

- will be used for auditing or program evaluation internally by FSU; or
- must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA).
- is necessary for your medical treatment and you have consented to the disclosure of your information;
- is for other research

In addition, identifiable, sensitive information protected by this Certificate cannot be admissible as evidence or used for any purpose in any action, suit, or proceeding without your consent.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not protect against the required reporting by FSU staff of information on suspected child abuse, reportable communicable diseases, and/or possible threat of harm to self or others.

Data for future use

The research team, authorized staff, and government agencies that run this type of research may have access to research data and records in order to check on the research. Research records given to approved researchers will not have your name, phone number, or email address. If a researcher requests our data, they will be special permission from the Research Compliance Administrator. Publications and/or presentations that result from this study will not identify you by name, phone number, or email. Data collected during this research study may be used for future research purposes. The data stored will not have your name, phone number, or email.

Your answers will be kept private – the data will be collected and stored securely at our research offices. Identifying facts such as your name, email, address, and phone number will be collected for research purposes. We will only use this to contact you for the purposes of this study.

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Data that cannot be linked to you individually (i.e., de-identified data) will be kept indefinitely; this data will be saved for future use and may be shared with other researchers. By being part of study, you are agreeing to allow us to save and share your anonymous data.

Biological samples collected for the purposes of this study will not be used to conduct any future research. They will be destroyed after analysis is completed.

At the end of the study, data collected will be made available, in accordance with the NIH Data Sharing Policy (http://grants.nih.gov/grants/policy/data_sharing). These data will be saved for future use and may be shared with other researchers. By participating in this study, you are agreeing to allow us to save and share your data anonymously.

Voluntary nature of the study
Taking part in this study is voluntary. You may choose not to take part in this study, or if you decide to take part, you can change your mind later and withdraw from the study. Questions in the computer survey cannot be skipped, but if you do not want to answer a question in the computer survey, you may just close the survey link. The survey will then remain incomplete. If you have an incomplete survey, your participation in the study will still continue unless you decide to withdraw from the study. You can withdraw from the study at any time. Your decision to withdraw will not change any present or future relationships with Florida State University, Hunter College, the health clinic or any of their affiliates.

It is important to the study that we continue collecting data at follow-up assessments. If you decide to withdraw from the study, please inform the study staff of your decision in writing or send an email to YMHPatn@prideresearch.org. We will ask you about whether you would be willing to continue with the follow-up study assessments but you may choose not to continue. We will also ask you about your decision to withdraw your participation in order to get your feedback about ways to help improve future studies. Because withdrawing data threatens the scientific integrity of the study, we plan to securely store and later use all of the data collected prior to your withdrawal. The data will be used in analyses to address the aims of the study.

Contacts and questions
If you have any questions about this study now or in the future, you may contact the following Principal Investigators: Tyrel Starks, PhD, at Hunter College by telephone at (212) 206-7919, or Angulique Outlaw, PhD (313) 577-0792.

If you would like to talk to someone other than the Principal Investigator, you are encouraged to contact the Florida State University Institutional Review Board (IRB) at 2010 Levy Street, Research Building B, Suite 276, Tallahassee, FL 32306-2742, or 850-644-8633, or by email at humansubjects@fsu.edu

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You will be given a copy of this information to keep for your records.

Statement of Consent/Assent:

I have read the above information. I have asked questions and received answers. I consent/assent to participate in this study.

_____ _____
Signature of Research Subject Date

_____
Printed Name of Research Subject

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

Do you agree to allow us to keep your email address and contact you about future research opportunities in the next five years? Please place your initials below next to your choice.

_____ Yes, you may keep my email address and contact me about future research opportunities in the next five years.

_____ No, you may not keep my email address and you may not contact me about future research opportunities in the next five years.

FLORIDA STATE UNIVERSITY

CONSENT/ASSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Comparative effectiveness trial of clinic-based delivery of an HIV risk reduction intervention (YMHP) for YMSM

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Young Men's Health PROJECT

Introduction

You are invited to be in a research study of an HIV- risk reduction program called the Young Men's Health Project (YMHP). Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone on the research team.

Key Information about the research study

Things you should know:

- The purpose of this study is to deliver and test an HIV risk reduction program among HIV-negative young men who have sex with men (YMSM). If you choose to participate, you will be asked to complete 5 surveys, 4 sessions of YMHP with a trained community health worker, and return to us for HIV and STI testing 2 times.
- Due to COVID-19, participants have the option to complete this research study in-office face to face, in-office virtually in separate assessment rooms, or virtually from home with STI testing in-office, or virtual from home with STI testing at home.
- Risks or discomforts from this research include feeling uncomfortable discussing topics including HIV and sexual behavior or substance use as well as feeling minor pain from the HIV and STI tests.
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Please take the time to read this entire form and ask questions before deciding whether to take part in this research project.

Why is this study being done?
This study is being conducted by Lawrence Friedman, MD at University of Miami and Tyrel Starks, Ph.D. at Hunter College, The City University of New York (CUNY). It is funded by The National Institute of Health (NIH).

The purpose of this study is to deliver and test an HIV risk reduction program among HIV-negative young men who have sex with men (YMSM). This program, called the Young Men's Health Project (YMHP), is a program focused on reducing the risk of getting HIV that has already shown to be effective in research settings. This research project will explore how this program works in "real world" clinics, and will compare the program being delivered two different ways: in person (at clinic) or remotely (over the phone, by video chat such as Skype or FaceTime).

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How many people are expected to take part in this study?
We will enroll 180 participants in total across three sites. In addition to enrolling 60 participants at University of Miami we will enroll 60 participants at both Wayne State University in Detroit and Children's Hospital of Philadelphia.

Study procedures
If you agree to be in the study, you will participate in the YMHP program in person or remotely depending on the preference of you or the study team and which group you are randomly assigned to for participation (like flipping a coin). You will be part of a group of 180 participants who are taking part in the program at three sites nationally.

If you agree to take part in this study, you will complete the following activities:

(1) **Baseline (first) visit**: After providing your consent to participate either in person or virtually, you will complete a confidential computer-based survey at this clinic that will ask about your drug and alcohol use, sexual behavior and general thoughts and feelings. This will take about 45 minutes to complete. If eligible to continue you will participate in STI testing (testing for sexually transmitted infections) and take a confidential urine drug test. STI testing will consist of a urine

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New York, NY, USA

sample and an anal self-swab of your rectal mucosa, and a finger prick or a blood draw may be performed for syphilis testing. This testing may be done in office or at home. If you elect to do testing at home, the study team or Molecular Labs will send you a testing kit to the address you specify. It will contain an Oraquick HIV test, supplies to collect urine and rectal swab for ST Testing, and a Dried Blood Spot Card for Syphilis testing. At this visit you will also complete Session 1 of the YMHP program. This session will be focused on either sexual risk or substance use and will be audio recorded. The entire baseline visit may take 3-4 hours to complete. If attending the Baseline visit at the office is not possible, you may be asked to do the Baseline visit virtually over HIPAA Compliant Zoom.

(2) YMHP sessions: You will be randomized (like flipping a coin) into one of two study groups: you will either complete four sessions of YMHP counseling or receive HIV test and counseling only. If you are assigned to YMHP sessions, you will complete session 1 of the YMHP program today. This session will be focused on either sexual risk or substance use and will be audio recorded. You will then complete 3 additional YMHP sessions focused on sexual risk and substance use. The sessions can be completed in person or remotely depending on your choice or the study team's choice. Each of these sessions will be audio recorded and will take about 40-60 minutes to complete. No video will be recorded. If you are assigned to HIV testing only, you should have recently received a HIV test at this clinic. We will ensure you are referred to relevant services that you may find beneficial. You will not need to come back until the post-test assessment. You may complete 4 sessions of YMHP after your 9 month follow-up.

(3) Immediate post-test assessment: Three months after your baseline appointment you will be scheduled to complete an immediate post-test assessment. During this assessment you will complete a confidential computer-based survey about your drug and alcohol use, sexual behavior and general thoughts and feelings. This survey can be completed at the clinic or by using a survey link we send to you electronically. This survey will be similar to the baseline survey and it will take about 45 minutes to complete.

(4) Follow up assessments: There will be three additional follow up assessments for you to complete. These follow up assessments will occur in three month intervals until approximately 9 months after your post intervention assessment (i.e. 3 months, 6, months, and 9 months).

The 3 month and 9 month follow up assessments include completing a confidential computer-based survey to be completed at home or in-office and require a confidential urine drug test, HIV and STI testing. The urine drug test, HIV and STI testing can be performed at this clinic or by using a self-test kit we or Molecular Labs will mail to your home if you choose. If you do not complete the 3 month or 9 month urine drug test, Oraquick HIV and STI testing you will be asked to complete these tests at your next assessment. If you complete Oraquick testing, we may conduct this testing with you over HIPAA Compliant Zoom.

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The HIV test will test for the presence of antibodies to HIV or HIV antigens. If the result is positive for HIV, you may be referred for a confirmatory HIV test when necessary. A YMHP staff member (from clinic Hunter College) trained in HIV testing and counseling will discuss the meaning of the test results with you, and explain the importance of timely access to health care, including antiretroviral therapy. If you test positive for an STI from a test at the clinic you will receive referrals for treatment from a trained YMHP clinic research staff member. If you test positive for an STI at home a trained member from the YMHP research staff Hunter College or from our clinic will contact you by phone or email to inform you of these results and refer you to treatment services located near your home. Urine drug test results will be provided to you upon request.

The 6 month assessment does not require urine drug tests and HIV or STI testing so therefore these assessments can be completed using an electronic link we send to you or you can complete the confidential computer-based survey at clinic if you choose. This survey will be similar to the baseline survey and it will take about 45 minutes to complete.

As part of this study you may be invited to take part in a one-on-one confidential interview with a member of our research staff to learn about your experience with participation in this research. This interview will be audio recorded. If you are invited but are not interested in participating in the one-on-one interview, you may decline and still continue in the study otherwise.

How long will I be in the study?
In total you will be in the study for approximately 12-months.

Risks of study participation
The risks and discomfort associated with participation in this study are no greater than those ordinarily encountered in daily life. The topics discussed both in the program sessions and the assessments are of a sensitive nature. Some people may feel uncomfortable talking and answering questions about topics including HIV and sexual behavior or substance use.

There is also a risk that your parents, family members or others will learn about your sexual orientation or sexual activity based on your participation in this research study. If you choose at-home HIV/STI testing, kits may be mailed to your home address. YMHP research staff will allow your kit to be shipped to an alternate location deemed as a safe space, such as a youth center, and will require you to speak with a trained staff member to ensure these arrangements are both safe and allowable. We are excluding those aged 17 years and below from participating in at-home testing at this site, taking into account FDA age approval for OraQuick and Florida state law on age of sexual consent.

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In addition, you may experience some minor pain as a result of the swab for STI testing and finger prick for the HIV test and syphilis test. If syphilis testing is performed via a needle stick, a trained phlebotomist will perform the needle stick to minimize the risk of bruising or infection. There is a very slight risk of developing an infection at the site of the needle stick. In addition, in order to minimize potential discomfort from swabbing procedures necessary for STI testing, clinic staff will provide you with instructions on how to properly perform the swab yourself to collect specimens. Self-swabs have been routinely performed both within and outside of medical settings, therefore potential risks are no greater than those encountered during routine medical exams.

In addition to the other possible harms or discomforts related to research that we told you about, there may be risks with using web-based or online programs. First, someone may try to interfere or tamper with our collection of information from you. Second, after we collect information from you, someone may see or take information about you without permission. If any of these things happen, your privacy and the confidentiality of the information that you provide to us may be violated.

In addition to other possible harms or discomforts related to research that we told you about, there may be risks by having you take part in our face-to-face study activities during this time of the Coronavirus emergency. First, face-to-face activities and contact with other persons may increase the risk of getting Coronavirus. No one is yet quite sure how easily Coronavirus passes from person to person, how to know for certain when someone has or does not have Coronavirus, or what works best at preventing Coronavirus from spreading. Second, getting Coronavirus may result in a person being isolated or quarantined at home and away from work, family and other activities. Third, Coronavirus is, a serious illness that may require medical care including hospital care, long-term disability, and even death.
Fourth, certain persons are at higher risk for severe illness from Coronavirus, and these persons are not permitted to take part in our study.

Persons thought to be at higher risk include:
• Being 65 years of age or older
• Prior or current exposure to persons that have Coronavirus whether or not they know it
• Persons of any age with serious medical conditions such as diabetes, and heart, lung, kidney or liver disease, or persons who are severely obese
• Persons who have poor immunity, such as persons under cancer treatment or who have other conditions with weakened immune systems
• People who reside in nursing homes or other long-term care facilities

We will therefore be asking some questions to screen all research participants and study staff to see who may be at risk of severe illness, or who have been exposed to Coronavirus. Even after we ask these questions, if you think that at any time before or during this study you may have been exposed to Coronavirus or are at risk of severe illness, then we will ask you not to take part in this study, so please let us know.

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While we will take steps to protect you from exposure to Coronavirus when you take part in our face-to-face activities, there is always the chance that you may still be exposed.

Finally, in order to reduce exposure to Coronavirus, we will ask you to stay at least six feet away from anyone else, including us, during our activities; wear a special mask to cover your mouth and nose; wear gloves to cover your hands; wear other equipment to cover your head and body; sit behind a wall or in another room nearby; wash and sanitize your hands; not to touch your face or anything else during our study activities unless we say it is OK. These steps are required. Having to do these things may not be comfortable for you and may cause you to be worried or stressed.

In addition to the risks of these Coronavirus-related harms or discomforts, this research may have risks of other Coronavirus-related harms or discomforts that are unknown at this time. If in the future we become aware of any additional harms or discomforts that may affect you, we will tell you.

Because this is a research study, there may be additional risks that we cannot identify at this time.

Benefits of study participation
The benefits to study participation are that you may learn more about yourself, your sexual behavior, your drug and alcohol use and other thoughts, feelings and behaviors. You are also helping the YMHP research team to develop a program to reduce the risk of exposure to HIV among young men who sex with men (YMSM), which will likely benefit other members of the community.

Alternatives to study participation
There are no therapeutic alternatives available at this time. An alternative is for you not to participate in this research study. Participants always have the option not to participate in this study, and referrals to other services provided by University of Miami are available to all study participants.

Ending the study
Your participation in this study is entirely voluntary. If you decide to leave the study, please contact the Site PI to inform themof your decision. Because withdrawing data threatens the scientific integrity of the study, we plan to securely store and later use all of the previously collected data in analyses to address the aims of the study. It is also important to the study that we continue collecting data at the follow-up assessment. We will ask you about whether you would be willing to continue with the follow-up assessment portion of the study, but you may choose not to continue. We will also ask you about your decision to withdraw your participation in this study in order to get your feedback about ways to help improve future studies.

We may end your participation for a number of reasons:

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1. During the course of the assessment it becomes clear that you do not meet study eligibility criteria,
2. Physical or psychological problems arise which would interfere with your voluntary participation in this study,
3. If we feel that it is in the best interests of your health, and/or
4. If we feel you are providing inaccurate or false information.

In addition, the research team may dismiss you if you engage in any hostile behavior toward the staff or if we find you are ineligible after completing your baseline appointment today.

Study costs/compensation
There will be no costs to you for your participation in this research study. For taking part in this research study, you will be paid for your time for both the YMHP sessions and assessment visits as follows, for a total of $275 if you complete the entire study.

Visit	Compensation amount
Baseline survey, urine drug test, STI and HIV testing and YMHP Session 1	$50 ($25 for completing the computer-based survey and $25 for completing first YMHP session and urine drug test, HIV and STI tests). $5 cash will also be provided for transportation costs or if you test at home and return the testing kit.
YMHP Program Sessions 2-4	$10 for each of the three YMHP sessions ($30 total). If the baseline and three additional YMHP sessions are completed, you will receive an additional $20.
Post-test assessment	$25 computer-based survey only
3-month assessment	$50 ($25 for completing the computer-based survey and $25 for completing urine drug test, HIV and STI testing). $5 cash will also be provided for transportation costs or if you test at home and return the testing kit.
6-month assessment	$25 computer-based survey only
9-month assessment	$50 ($25 for completing the computer-based survey and $25 for completing urine drug test, HIV and STI testing). $5 cash will also be provided for transportation costs or if you test at home and return the testing kit.

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Qualitative Interview (optional)	$25 phone interview

You will be paid the amount specified above via gift card or cash.

You may refer members of your social network to participate in the study. For each person you recruit who screens eligible after the baseline visit, you will receive a $10 e-gift card incentive. You will receive this $10 incentive for up to 5 of these referrals for a maximum of $50. You will be given either a card with your unique number or a special link you can share with your friends. Study staff will know you referred that participant and compensate you accordingly.

Who can profit from study results?
No conflicts or gains have been identified in connection with this study. Florida State University reviews staff researchers for conflicts of interest.

Members of the research team working on this study may have up to $15,000 of stock in the companies that make products used in this study. This is allowed under federal rules and is not a conflict of interest.

How will my samples and data be used?
The biological specimens collected for the purposes of this study will not be used to conduct any future research and will be destroyed after analysis is completed. Your survey responses will be used to help the YMHP research team to develop a program to reduce the risk of exposure to HIV among young men who sex with men (YMSM), which will likely benefit other members of the community.

Confidentiality
Every effort will be made to keep all of the material related to you private and confidential. You will be assigned a code number, and all study related data and any other materials that may be generated by participation will be identified only by that code number. Any materials that match a code number to your name will be kept in a separate, locked file located at our clinic office and Hunter College. Your identity will be kept confidential in any presentation or publication of the results of this study. Data that cannot be linked to you individually (i.e., de-identified) will be analyzed by members of the research team and will be kept indefinitely; these data will be saved for future use and may be shared with other researchers. By participating in this study, you are agreeing to allow us to save and share your data anonymously.

However, research information that identifies you may be shared with the FSU Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to

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research, including people on behalf of the National Institutes of Health (NIH) and the Office for Human Research Protections (OHRP).

You will be asked to provide contact information which will help the YMHP researchers at our clinic office and at Hunter College reach you to complete follow up assessments. This information includes your name, address, telephone number, email address and other facts that could identify you. The contact information will be kept separate from your research records. The YMHP researchers at Hunter College may use this information to send you links to the surveys, send a reminder about upcoming visits or contact you to complete this research, for example if you relocate or don't have access to a clinic. This information will be stored in a secure database at Hunter College.

Additionally, if you test positive with HIV or an STI, you should understand that Florida state laws require healthcare providers and clinical laboratories to report the test results with your personally identifying information to the local health department. The study team is required to follow these laws.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

In addition to the steps we are taking to protect your privacy and confidentiality overall, we will also take other steps to keep people from tampering with our web-based or online activities or taking information without your permission.

First, we only use web-based and online programs that follow the laws and best standards for protecting against tampering or unauthorized access. Second, we limit who may have access to our HIPAA Compliant Zoom account to only persons like you who are invited to take part and to members of the study team. Once the Zoom session is closed to taking part, no one else besides the study team has access.

Despite taking all these steps to protect your privacy and the confidentiality of your identifiable information, we are not able to guarantee that people will be unable to tamper with our web-based or online activities or take information without your permission.

Certificate of Confidentiality

To help protect your privacy, a Certificate of Confidentiality has been obtained from NIH to help others from learning about your participation in this study. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena.
You should also know that there are several circumstances in which the Certificate does not provide coverage. These include when information:

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- will be used for auditing or program evaluation internally by FSU; or
- must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA).
- is necessary for your medical treatment and you have consented to the disclosure of your information;
- is for other research

In addition, identifiable, sensitive information protected by this Certificate cannot be admissible as evidence or used for any purpose in any action, suit, or proceeding without your consent.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not protect against the required reporting by FSU staff of information on suspected child abuse, reportable communicable diseases, and/or possible threat of harm to self or others.

Data for future use

The research team, authorized staff, and government agencies that run this type of research may have access to research data and records in order to check on the research. Research records given to approved researchers will not have your name, phone number, or email address. If a researcher requests our data, they will be special permission from the Research Compliance Administrator. Publications and/or presentations that result from this study will not identify you by name, phone number, or email. Data collected during this research study may be used for future research purposes. The data stored will not have your name, phone number, or email.

Your answers will be kept private – the data will be collected and stored securely at our research offices. Identifying facts such as your name, email, address, and phone number will be collected for research purposes. We will only use this to contact you for the purposes of this study.

Data that cannot be linked to you individually (i.e., de-identified data) will be kept indefinitely; this data will be saved for future use and may be shared with other researchers. By being part of study, you are agreeing to allow us to save and share your anonymous data.

Biological samples collected for the purposes of this study will not be used to conduct any future research. They will be destroyed after analysis is completed.

At the end of the study, data collected will be made available, in accordance with the NIH Data Sharing Policy (http://grants.nih.gov/grants/policy/data_sharing). These data will be saved for future use and may

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be shared with other researchers. By participating in this study, you are agreeing to allow us to save and share your data anonymously.

Voluntary nature of the study
Taking part in this study is voluntary. You may choose not to take part in this study, or if you decide to take part, you can change your mind later and withdraw from the study. Questions in the computer survey cannot be skipped, but if you do not want to answer a question in the computer survey, you may just close the survey link. The survey will then remain incomplete. If you have an incomplete survey, your participation in the study will still continue unless you decide to withdraw from the study. You can withdraw from the study at any time. Your decision to withdraw will not change any present or future relationships with Florida State University, Hunter College, the health clinic or any of their affiliates.

It is important to the study that we continue collecting data at follow-up assessments. If you decide to withdraw from the study, please inform the study staff of your decision in writing or send an email to YMHPatn@prideresearch.org. We will ask you about whether you would be willing to continue with the follow-up study assessments but you may choose not to continue. We will also ask you about your decision to withdraw your participation in order to get your feedback about ways to help improve future studies. Because withdrawing data threatens the scientific integrity of the study, we plan to securely store and later use all of the data collected prior to your withdrawal. The data will be used in analyses to address the aims of the study.

Contacts and questions
If you have any questions about this study now or in the future, you may contact the following Principal Investigators: Tyrel Starks, PhD, (212) 206-7919, or Lawrence Friedman, MD, (305) 243-5880.

If you would like to talk to someone other than the Principal Investigator, you are encouraged to contact the Florida State University Institutional Review Board (IRB) at 2010 Levy Street, Research Building B, Suite 276, Tallahassee, FL 32306-2742, or 850-644-8633, or by email at humansubjects@fsu.edu

You will be given a copy of this information to keep for your records.

Statement of Consent/Assent:

I have read the above information. I have asked questions and received answers. I consent/assent to participate in this study.

_____ _____
Signature of Research Subject Date

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_____
Printed Name of Research Subject

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

Do you agree to allow us to keep your email address and contact you about future research opportunities in the next five years? Please place your initials below next to your choice.

_____ Yes, you may keep my email address and contact me about future research opportunities in the next five years.

_____ No, you may not keep my email address and you may not contact me about future research opportunities in the next five years.

Children's Hospital of Philadelphia

YMHP INFORMED CONSENT/ASSENT

The Children's Hospital of Philadelphia
Consent to Participate in a Research Study

FSU IRB Study # 2017.22494

Title of Study: ATN 145: Comparative effectiveness trial of clinic-based delivery of an HIV risk reduction intervention (YMHP) for YMSM

Site Principal Investigator: Mary Tanney, MPH, CRNP
Site Principal Investigator: Department: Division of Adolescent Medicine
Site Principal Investigator Phone number: 267-315-6833
Site Principal Investigator Email Address: tanney@email.chop.edu

Sponsor: Florida State University (FSU)
Hunter College, New York
Funding Source: National Institutes of Health (NIH)
Study Contact: Kim Desir
Study Contact phone: 215-910-0071
Study Contact email: desirk@email.chop.edu

Young Men's Health PROJECT

Introduction

You are invited to be in a research study of an HIV- risk reduction program called the Young Men's Health Project (YMHP). Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone on the research team.

Key Information about the research study

Things you should know:

- The purpose of this study is to deliver and test an HIV risk reduction program among HIV-negative young men who have sex with men (YMSM). If you choose to participate, you will be asked to complete 5 surveys, 4 sessions of YMHP with a trained community health worker, and return to us for HIV and STI testing 2 times.
- Due to COVID-19, participants have the option to complete this research study in-office face to face, in-office virtually in separate assessment rooms, virtually from home with STI testing in-office, or virtual from home with STI testing at home.
- Risks or discomforts from this research include feeling uncomfortable discussing topics including HIV and sexual behavior or substance use as well as feeling minor pain from the HIV and STI tests.
- The study will help to develop a program to reduce the risk of exposure to HIV among young men who sex with men.
- Taking part in this research project is voluntary. You don't have to participate and can stop at any time.

Please take the time to read this entire form and ask questions before deciding whether to take part in this research project.

Why is this study being done?

This study is being conducted by Mary Tanney, MPH, CRNP at the Children's Hospital of Philadelphia and Tyrel Starks, Ph.D. at Hunter College, The City University of New York (CUNY). It is funded by The National Institute of Health (NIH).

The purpose of this study is to deliver and test an HIV risk reduction program among HIV-negative young men who have sex with men (YMSM). This program, called the Young Men's Health Project (YMHP), is a program focused on reducing the risk of getting HIV that has already shown to be effective in research settings. This research project will explore how this program works in "real world" clinics, and will compare the program being delivered two different ways: in person (at clinic) or remotely (over the phone, by video chat such as Skype or FaceTime).

Why are you being asked to take part in this study?

You were selected as a possible participant in the YMHP because you have identified as an HIV-negative young man who has sex with other men, have used drugs or alcohol previously, and are between the ages of 15 and 24. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

How many people are expected to take part in this study?

We will enroll 180 participants in total across three sites. In addition to enrolling 60 participants at the Children's Hospital of Philadelphia we will enroll 60 participants at both the University of Miami and Wayne State University.

Study procedures

If you agree to be in the study, you will participate in the YMHP program in person or remotely depending on the preference of you or the study team and which group you are randomly assigned to for participation (like flipping a coin). You will be part of a group of 180 participants who are taking part in the program at three sites nationally.

If you agree to take part in this study, you will complete the following activities:

(1) **Baseline (first) visit**: After providing your consent to participate either in person or virtually, you will complete a confidential computer-based survey at this clinic that will ask about your drug and alcohol use, sexual behavior and general thoughts and feelings. This will take about 45 minutes to complete. If eligible to continue you will participate in STI testing (testing for sexually transmitted infections) and take a confidential urine drug test. STI testing will consist of a urine sample, an anal self-swab of your rectal mucosa and a finger prick or a blood draw may be performed for syphilis testing. This testing may be done in office or at home. If you elect to do testing at home, the study team or Molecular Labs will send you a testing kit to the address you specify. It will contain an Oraquick HIV test, supplies to collect urine and rectal swab for ST Testing, and a Dried Blood Spot Card for Syphilis testing. At this visit you will also complete Session 1 of the YMHP program. This session will be focused on either sexual risk or substance use and will be audio recorded. The entire baseline visit may take 3-4 hours to complete. If attending the Baseline visit at the office is not possible, you may be asked to do the Baseline visit virtually over HIPAA Compliant Zoom.

(2) YMHP sessions: You will be randomized (like flipping a coin) into one of two study groups: you will either complete four sessions of YMHP counseling or receive HIV test and counseling only. If you are assigned to YMHP sessions, you will complete session 1 of the YMHP program today. This session will be focused on either sexual risk or substance use and will be audio recorded. You will then complete 3 additional YMHP sessions focused on sexual risk and substance use. The sessions can be completed in person or remotely depending on your choice or the study team's choice. Each of these sessions will be audio recorded and will take about 40-60 minutes to complete. No video will be recorded. If you are assigned to HIV testing only, you should have recently received a HIV test at this clinic. We will ensure you are referred to relevant services that you may find beneficial. You will not need to come back until the post-test assessment. You may complete 4 sessions of YMHP after your 9 month follow-up.

(3) Immediate post-test assessment: Three months after your baseline appointment you will be scheduled to complete an immediate post-test assessment. During this assessment you will complete a confidential computer-based survey about your drug and alcohol use, sexual behavior and general thoughts and feelings. This survey can be completed at the clinic or by using a survey link we send to you electronically. This survey will be similar to the baseline survey and it will take about 45 minutes to complete.

(4) Follow up assessments: There will be three additional follow up assessments for you to complete. These follow up assessments will occur in three month intervals until approximately 9 months after your post intervention assessment (i.e. 3 months, 6, months, and 9 months).

The 3 month and 9 month follow up assessments include completing a confidential computer-based survey to be completed at home or in-office and require a confidential urine drug test, HIV and STI testing. The urine drug test, HIV and STI testing can be performed at this clinicor by using a self-test kit we or Molecular Labs will mail to your home if you choose. If you do not complete the 3 month or 9 month urine drug test, Oraquick HIV and STI testing, you will be asked to complete these tests at your next assessment. If you complete Oraquick testing, we may conduct this testing with you over HIPAA Compliant Zoom.

The HIV test will test for the presence of antibodies to HIV or HIV antigens. If the result is positive for HIV, you may be referred for a confirmatory HIV test when necessary. A YMHP staff member (from the clinic or Hunter College) trained in HIV testing and counseling will discuss the meaning of the test results with you, and explain the importance of timely access to health care, including antiretroviral therapy. If you test positive for an STI from a test at the clinic you will receive referrals for treatment from a trained YMHP clinic research staff member. If you test positive for an STI at home a trained member from the YMHP research staff at Hunter College or from our clinic will contact you by phone or email to inform you of these results and refer you to treatment services located near your home. Urine drug test results will be provided to you upon request.

The 6 month assessment does not require urine drug tests or HIV and STI testing so therefore these assessments can be completed using an electronic link we send to you or you can complete the confidential computer-based survey at clinic if you choose. This survey will be similar to the baseline survey and it will take about 45 minutes to complete.

As part of this study you may be invited to take part in a one-on-one confidential interview with a member of our research staff to learn about your experience with participation in this research. This interview will be audio recorded. If you are invited but are not interested in participating in the one-on-one interview, you may decline and still continue in the study otherwise.

How long will I be in the study?
In total you will be in the study for approximately 12-months.

Risks of study participation
The risks and discomfort associated with participation in this study are no greater than those ordinarily encountered in daily life. The topics discussed both in the program sessions and the assessments are of a sensitive nature. Some people may feel uncomfortable talking and answering questions about topics including HIV and sexual behavior or substance use.

There is also a risk that your parents, family members or others will learn about your sexual orientation or sexual activity based on your participation in this research study. If you choose at-home HIV/STI testing, kits may be mailed to your home address. YMHP research staff will allow your kit to be shipped to an alternate location deemed as a safe space, such as a youth center, and will require you to speak with a trained staff member to ensure these arrangements are both safe and allowable. We are excluding those aged 16 years and below from participating in at-home testing at this site, taking into account FDA age approval for OraQuick and Pennsylvania state law on age of sexual consent.

In addition, you may experience some minor pain as a result of the swab for STI testing and finger stick for the HIV test and syphilis test. If syphilis testing is performed via a needle stick, a trained phlebotomist

will perform the needle stick to minimize the risk of bruising or infection. There is a very slight risk of developing an infection at the site of the needle stick. In addition, in order to minimize potential discomfort from swabbing procedures necessary for STI testing, clinic staff will provide you with instructions on how to properly perform the swab yourself to collect specimens. Self-swabs have been routinely performed both within and outside of medical settings, therefore potential risks are no greater than those encountered during routine medical exams.

In addition to the other possible harms or discomforts related to research that we told you about, there may be risks with using web-based or online programs. First, someone may try to interfere or tamper with our collection of information from you. Second, after we collect information from you, someone may see or take information about you without permission. If any of these things happen, your privacy and the confidentiality of the information that you provide to us may be violated.

In addition to other possible harms or discomforts related to research that we told you about, there may be risks by having you take part in our face-to-face study activities during this time of the Coronavirus emergency. First, face-to-face activities and contact with other persons may increase the risk of getting Coronavirus. No one is yet quite sure how easily Coronavirus passes from person to person, how to know for certain when someone has or does not have Coronavirus, or what works best at preventing Coronavirus from spreading. Second, getting Coronavirus may result in a person being isolated or quarantined at home and away from work, family and other activities. Third, Coronavirus is, a serious illness that may require medical care including hospital care, long-term disability, and even death.
Fourth, certain persons are at higher risk for severe illness from Coronavirus, and these persons are not permitted to take part in our study.

Persons thought to be at higher risk include:
• Being 65 years of age or older
• Prior or current exposure to persons that have Coronavirus whether or not they know it
• Persons of any age with serious medical conditions such as diabetes, and heart, lung, kidney or liver disease, or persons who are severely obese
• Persons who have poor immunity, such as persons under cancer treatment or who have other conditions with weakened immune systems
• People who reside in nursing homes or other long-term care facilities

We will therefore be asking some questions to screen all research participants and study staff to see who may be at risk of severe illness, or who have been exposed to Coronavirus. Even after we ask these questions, if you think that at any time before or during this study you may have been exposed to Coronavirus or are at risk of severe illness, then we will ask you not to take part in this study, so please let us know.

While we will take steps to protect you from exposure to Coronavirus when you take part in our face-to-face activities, there is always the chance that you may still be exposed.

Finally, in order to reduce exposure to Coronavirus, we will ask you to stay at least six feet away from anyone else, including us, during our activities; wear a special mask to cover your mouth and nose; wear gloves to cover your hands; wear other equipment to cover your head and body; sit behind a wall or in another room nearby; wash and sanitize your hands; not to touch your face or anything else during our

study activities unless we say it is OK. These steps are required. Having to do these things may not be comfortable for you and may cause you to be worried or stressed.

In addition to the risks of these Coronavirus-related harms or discomforts, this research may have risks of other Coronavirus-related harms or discomforts that are unknown at this time. If in the future we become aware of any additional harms or discomforts that may affect you, we will tell you.

Because this is a research study, there may be additional risks that we cannot identify at this time.

Benefits of study participation
The benefits of study participation are that you may learn more about yourself, your sexual behavior, your drug and alcohol use and other thoughts, feelings and behaviors. You are also helping the YMHP research team to develop a program to reduce the risk of exposure to HIV among young men who sex with men (YMSM), which will likely benefit other members of the community.

Alternatives to study participation
There are no therapeutic alternatives available at this time. An alternative is for you not to participate in this research study. Participants always have the option not to participate in this study, and referrals to other services provided by CHOP are available to all study participants.

Ending the study
Your participation in this study is entirely voluntary. If you decide to leave the study, please contact the Site PI to inform themof your decision. Because withdrawing data threatens the scientific integrity of the study, we plan to securely store and later use all of the previously collected data in analyses to address the aims of the study. It is also important to the study that we continue collecting data at the follow-up assessment. We will ask you about whether you would be willing to continue with the follow-up assessment portion of the study, but you may choose not to continue. We will also ask you about your decision to withdraw your participation in this study in order to get your feedback about ways to help improve future studies.

We may end your participation for a number of reasons:

1. During the course of the assessment it becomes clear that you do not meet study eligibility criteria,
2. Physical or psychological problems arise which would interfere with your voluntary participation in this study,
3. If we feel that it is in the best interests of your health, and/or
4. If we feel you are providing inaccurate or false information.

In addition, the research team may dismiss you if you engage in any hostile behavior toward the staff or if we find you are ineligible after completing your baseline appointment today.

Study costs/compensation
There will be no costs to you for your participation in this research study. For taking part in this research study, you will be paid for your time for both the YMHP sessions and assessment visits as follows, for a total of $275 if you complete the entire study:

Visit	Compensation amount
Baseline survey, urine drug test, STI and HIV testing and YMHP Session 1	$50 ($25 for completing the computer-based survey and $25 for completing first YMHP session and urine drug test, HIV and STI tests). $5 cash will also be provided for transportation costs or if you test at home and return the testing kit.
YMHP Program Sessions 2-4	$10 for each of the three YMHP sessions ($30 total). If the baseline and three additional YMHP sessions are completed, you will receive an additional $20.
Post-test assessment	$25 computer-based survey only
3-month assessment	$50 ($25 for completing the computer-based survey and $25 for completing urine drug test, HIV and STI testing). $5 cash will also be provided for transportation costs or if you test at home and return the testing kit.
6-month assessment	$25 computer-based survey only
9-month assessment	$50 ($25 for completing the computer-based survey and $25 for completing urine drug test, HIV and STI testing). $5 cash will also be provided for transportation costs or if you test at home and return the testing kit.
Qualitative Interview (optional)	$25 phone interview

You will be paid the amounts specified above via gift card.

You may refer members of your social network to participate in the study. For each person you recruit who screens eligible after the baseline visit, you will receive a $10 e-gift card incentive. You will receive this $10 incentive for up to 5 of these referrals for a maximum of $50. You will be given either a card with your unique number or a special link you can share with your friends. Study staff will know you referred that participant and compensate you accordingly.

Who can profit from study results?
No conflicts or gains have been identified in connection with this study. Florida State University reviews staff researchers for conflicts of interest.

Members of the research team working on this study may have up to $15,000 of stock in the companies that make products used in this study. This is allowed under federal rules and is not a conflict of interest.

How will my samples and data be used?
The biological specimens collected for the purposes of this study will not be used to conduct any future research and will be destroyed after analysis is completed. Your survey responses will be used to help the YMHP research team to develop a program to reduce the risk of exposure to HIV among young men who sex with men (YMSM), which will likely benefit other members of the community.

Confidentiality
Every effort will be made to keep all of the material related to you private and confidential. You will be assigned a code number, and all study related data and any other materials that may be generated by participation will be identified only by that code number. Any materials that match a code number to your name will be kept in a separate, locked file located at our clinic office and Hunter College. Your identity will be kept confidential in any presentation or publication of the results of this study. Data that cannot be linked to you individually (i.e., de-identified) will be analyzed by members of the research team and will be kept indefinitely; these data will be saved for future use and may be shared with other researchers. By participating in this study, you are agreeing to allow us to save and share your data anonymously.

However, research information that identifies you may be shared with the FSU Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of the National Institutes of Health (NIH) and the Office for Human Research Protections (OHRP).

You will be asked to provide contact information which will help the YMHP researchers at our clinic office and at Hunter College reach you to complete follow up assessments. This information includes your name, address, telephone number, email address and other facts that could identify you. The contact information will be kept separate from your research records. The YMHP researchers at Hunter College may use this information to send you links to the surveys, send a reminder about upcoming visits or contact you to complete this research, for example if you relocate or don't have access to a clinic. This information will be stored in a secure database at Hunter College.

Additionally, if you test positive with HIV or an STI, you should understand that Pennsylvania state laws require healthcare providers and clinical laboratories to report the test results with your personally identifying information to the local health department. The study team is required to follow these laws.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

In addition to the steps we are taking to protect your privacy and confidentiality overall, we will also take other steps to keep people from tampering with our web-based or online activities or taking information without your permission.

First, we only use web-based and online programs that follow the laws and best standards for protecting against tampering or unauthorized access. Second, we limit who may have access to our HIPAA Compliant Zoom account to only persons like you who are invited to take part and to members of the study team. Once the Zoom session is closed to taking part, no one else besides the study team has access.

Despite taking all these steps to protect your privacy and the confidentiality of your identifiable information, we are not able to guarantee that people will be unable to tamper with our web-based or online activities or take information without your permission.

Certificate of Confidentiality
To help protect your privacy, a Certificate of Confidentiality has been obtained from NIH to help others from learning about your participation in this study. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena.

You should also know that there are several circumstances in which the Certificate does not provide coverage. These include when information:

- will be used for auditing or program evaluation internally by FSU; or
- must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA).
- is necessary for your medical treatment and you have consented to the disclosure of your information;
- is for other research

In addition, identifiable, sensitive information protected by this Certificate cannot be admissible as evidence or used for any purpose in any action, suit, or proceeding without your consent.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not protect against the required reporting by FSU staff of information on suspected child abuse, reportable communicable diseases, and/or possible threat of harm to self or others.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, The Children's Hospital of Philadelphia will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives at Florida State University (FSU), Hunter College, The Children's Hospital of Philadelphia, research sponsors, or government agencies for purposes such as quality control or safety.

Every effort will be made to keep your participation in the study and any personal information about you private and confidential. However, absolute confidentiality cannot be guaranteed. For example, if a study staff member learns something that would immediately put you or others in danger, the study staff member is required by law to take steps to keep you and others safe. The law says we have to tell someone if you are in danger such as telling staff that you plan to hurt or kill yourself or someone else, if you reveal that a child or elderly person may be the victim of abuse or if you are a minor and are experiencing a legally reportable form of neglect, or sexual and/or physical abuse.

In addition, your records may be reviewed by certain agencies or people who make sure that the study staff are doing what they are supposed to and everyone in the study is being protected. Under the guidelines of the Federal Privacy Act, the sponsoring agency at the National Institutes of Health (NIH) and the FSU IRB may look at your records. If your study records are reviewed, your identity could become known to them. However, these persons are expected to maintain your individual confidentiality. This

means that they will not tell others information about you or that you are in the study. By signing this form, you are allowing such access.

You will be asked to provide contact information which will help the YMHP researchers at our clinic office and at Hunter College reach you to complete follow up assessments. This information includes your name, address, telephone number, email address and other facts that could identify you. The contact information will be kept separate from your research records. The YMHP researchers at Hunter College may use this information to send you links to the surveys, send a reminder about upcoming visits or contact you to complete this research, for example if you relocate or don't have access to a clinic. This information will be stored in a secure database at Hunter College.

Data for future use
The research team, authorized staff, and government agencies that run this type of research may have access to research data and records in order to check on the research. Research records given to approved researchers will not have your name, phone number, or email address. If a researcher requests our data, they will be special permission from the Research Compliance Administrator. Publications and/or presentations that result from this study will not identify you by name, phone number, or email. Data collected during this research study may be used for future research purposes. The data stored will not have your name, phone number, or email.

Your answers will be kept private – the data will be collected and stored securely at our research offices. Identifying facts such as your name, email, address, and phone number will be collected for research purposes. We will only use this to contact you for the purposes of this study.

Data that cannot be linked to you individually (i.e., de-identified data) will be kept indefinitely; this data will be saved for future use and may be shared with other researchers. By being part of study, you are agreeing to allow us to save and share your anonymous data.

Biological samples collected for the purposes of this study will not be used to conduct any future research. They will be destroyed after analysis is completed.

At the end of the study, data collected will be made available, in accordance with the NIH Data Sharing Policy (http://grants.nih.gov/grants/policy/data_sharing). These data will be saved for future use and may be shared with other researchers. By participating in this study, you are agreeing to allow us to save and share your data anonymously.

Voluntary nature of the study
Taking part in this study is voluntary. You may choose not to take part in this study, or if you decide to take part, you can change your mind later and withdraw from the study. Questions in the computer survey cannot be skipped, but if you do not want to answer a question in the computer survey, you may just close the survey link. The survey will then remain incomplete. If you have an incomplete survey, your participation in the study will still continue unless you decide to withdraw from the study. You can withdraw from the study at any time. Your decision to withdraw will not change any present or future relationships with Florida State University, Hunter College, the health clinic or any of their affiliates.

It is important to the study that we continue collecting data at follow-up assessments. If you decide to withdraw from the study, please inform the study staff of your decision in writing or send an email to YMHPatn@prideresearch.org. We will ask you about whether you would be willing to continue with the follow-up study assessments but you may choose not to continue. We will also ask you about your decision to withdraw your participation in order to get your feedback about ways to help improve future studies. Because withdrawing data threatens the scientific integrity of the study, we plan to securely store and later use all of the data collected prior to your withdrawal. The data will be used in analyses to address the aims of the study.

What if you are an employee of The Children's Hospital of Philadelphia?
Taking part in this research is not a part of your job duties, and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

What if you have any questions about the study?
You have the right to ask, and have answered, any questions you may have about this research at any time before, during or after your participation. If you have any questions, or concerns about this study now or in the future, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?
If you have any questions about the study call the Principal Investigator: Mary Tanney, MPH, CRNP (267) 315-6833 or the Study Coordinator Kim Desir at 215-910-0071. You may also talk to the study's Principal Investigator Tyrek Starks, PhD, at Hunter College by telephone at (212) 206-7919.

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously, if you wish, the Florida State University Institutional Review Board (IRB) at 2010 Levy Street, Research Building B, Suite 276, Tallahassee, FL 32306-2742, or 850-644-8633, or by email at humansubjects@fsu.edu

If you are a CHOP patient/subject and have questions about your rights or if you have a complaint, you can also call the CHOP office of Research Compliance at 215-590-2830.

You will be given a copy of this information to keep for your records.

Statement of Consent/Assent:

I have read the above information. I have asked questions and received answers. I consent/assent to participate in this study.

_____ _____
Signature of Research Subject Date

_____
Printed Name of Research Subject

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

Do you agree to allow us to keep your email address and contact you about future research opportunities in the next five years? Please place your initials below next to your choice.

_____ Yes, you may keep my email address and contact me about future research opportunities in the next five years.

_____ No, you may not keep my email address and you may not contact me about future research opportunities in the next five years.