Consent Form
Young Men's Health Project (YMHP): Examining community-based effectiveness of a substance use and HIV risk reduction intervention for young men of color (YMHP-CBO)

Sponsor: National Institute on Drug Abuse (NIDA)
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THE CITY UNIVERSITY OF NEW YORK
Hunter College

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title of Research Study: *Young Men's Health Project (YMHP)*

Principal Investigator: Tyrel Starks, Ph.D. Hunter College
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PURPOSE OF THE STUDY:

Dr. Tyrel Starks and his research staff from Hunter College, The City University of New York (CUNY) in partnership with BOOM!Health are doing a research study to better understand substance use and sexual risk taking among young men who have sex with men. The research study is funded by the National Institute for Drug Abuse. The purpose is to test the effectiveness of a type of counseling called Motivational Interviewing (MI) in a Community Based Organization (CBO) setting to help you better manage your drug and alcohol use and sexual health in an effort to prevent HIV and STIs. You have been asked to participate in this study because you have identified as a young man who has sex with other men, have used substances previously, and are between the ages of 15-29.

Key Information about the research study

- 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 6 surveys, 4 sessions of YMHP or one session of service referrals with a trained community health worker, and return to us for HIV and STI testing 2 times.
- 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.

PROCEDURES:

Should you choose to participate in this study, you may complete the following tasks.

1. At your first assessment today you will complete a computer-based survey that will ask about your substance use, sexual behavior and general thoughts and feelings. This will take about 45 minutes to complete. Your responses are confidential and will be stored under a code number assigned to all data you provide. You will be asked to complete a similar survey at your post intervention assessment and your 3-month, 6-month, and 9-month post intervention assessments.

2. You will also be asked to have Sexually Transmitted Infection (STI) tests performed today, which consists of a urine sample, an anal self-swab of your rectal mucosa, and a finger prick or a 1 tube (10ml) blood draw for syphilis testing. This should take about 15 minutes. Positive STI test results are also required to be reported to the New York State Department of Health, under the law. State law protects the confidentiality of your test results. You will also complete similar STI testing at the 3-month and 9-month post intervention assessments. If you do not complete the 3-month or 9-month HIV and STI testing, you will be asked to complete these tests at your next assessment.

3. 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 one session of enhanced treatment as usual as provided by a Health Educator. Your first session will take place today. Your assigned Health Educator will explain to you the details of your participation and if necessary you will collaboratively set up convenient meeting times. Each of the four YMHP sessions will be audio recorded and will take about 40-50 minutes to complete. These will happen weekly. If you are assigned to receive four YMHP sessions you will be reimbursed for your transportation costs and compensated with a food voucher for sessions 2-4. If you are assigned to receive four YMHP sessions, you will receive additional compensation upon completion of all four sessions. If you are assigned to enhanced treatment as usual, your session will be audio recorded and take 30-45 minutes. Your only session will take place today.

4. After your first assessment, you will participate in this project for a total of 12 months and will complete confidential computer-based surveys for 4 additional assessments (Post intervention, 3-month, 6 month, and 9-month post intervention). This survey can be completed at the CBO or Hunter College 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.

5. Three months from now, you may be invited to take part in a one-on-one confidential interview with a member of our research staff. 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. This is optional. This interview will be audio-recorded and take 30-45 minutes and will take place over the phone or in- person at your next appointment in the office.

6. You will be asked to complete an HIV to test for the presence of antibodies to HIV or HIV antigens. This will occur at the 3-month and 9-month post intervention assessments (6 months and 12 months after baseline). A staff member trained in HIV testing and counseling will perform the test. If the result is positive, you may need a confirmatory HIV test. A staff member 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. Should you receive a positive HIV test result, your result will be reported to the New York State Department of Health. The names of persons with HIV are reported to the State Health Department for tracking the epidemic and for planning services. State law protects the confidentiality of your test results and also protects you from discrimination based on your HIV status.

AUDIO RECORDING:

An audio recording will be taken of each of your four treatment sessions and one-on -one interview if you choose to participate in the interview. The audio recordings of the treatment sessions will be used by supervisors in order to provide supervision to Health Educators and for quality assurance. Only your study identification number will appear on the file name. All digital audio files will be stored electronically on a secure server that only Dr. Starks and his research team will have access to. The audio recordings will be kept for three years after you complete the study, at which point they will be destroyed. You can still participate if you do not agree to be audiotaped.

TIME COMMITMENT:

Your participation will last approximately 15 months in total.

POTENTIAL RISKS OR DISCOMFORTS:

There are no major risks from being in this study. As with any research study that collects information about you, there is a risk of breach of confidentiality. However, we will minimize that risk by assigning you a unique study identification number and using it as a pseudonym instead of your name. Your name, address, email, or social security number will not be collected on the survey, interview, or counseling sessions. A record that will link unique identification codes with names and contact information for participants will be accessible only to study staff and maintained off-line in a password-protected file on a secure server at our center and Hunter College. There is a slight chance that you may feel uncomfortable or embarrassed answering some of the questions that may arise in your conversations with the health educator.

In addition, you may experience some minor pain as a result of the swab for the STI testing and finger stick for the HIV test or syphilis testing. 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. They will collect 1 tube (10ml) of blood. 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, we 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.

If you are participating at BOOM!Health, your biological specimens may be tested through Callen-Lorde. To collect and process the specimens, Callen-Lorde will create clinical medical records if you currently do not have one and maintain them within Callen-Lorde's Electronic Health Records (EHR) system. All specimens will be labeled with a Clinic Medical Record Number (MR#), participant's last name and first name, and date of birth. To create the clinical medical record, you will need to sign a separate HIPAA Authorization Form. Callen-Lorde has strict guidelines in place to protect patient's

identities and health information. The only information from your medical record that Callen-Lorde will provide the research team is the results from the biological specimens collected as part of this research study.

POTENTIAL BENEFITS:

There are no direct benefits to you from this study. However, by participating in the sessions and completing surveys and interviews, you may learn more about yourself, your sexual behavior, substanceuse and other thoughts, feelings and behaviors. You are also helping Dr. Starks and his research team to develop a counseling 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.

ENDING PARTICIPATION IN THIS STUDY:

Your participation in this study is voluntary, and you may decide not to participate without prejudice, penalty, or loss of benefits to which you are otherwise entitled. If you choose to not be in the study or withdraw from the study, you can still receive care and all services from BOOM!Health. If you decide to leave the study, please contact the study staff to inform them of your decision. Although you may withdraw from the study, study data cannot be withdrawn. All remaining data will be securely stored and later used 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.

ALTERNATIVES TO 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 BOOM!Health are available to all study participants.

PAYMENT FOR PARTICIPATION:

For taking part in this research study, you will be paid for your time at each YMHP session and assessment visit as follows, up to a total of $245 in gift cards from Target, $16.50 in metro cards, and $21 in food vouchers if you complete the entire study. If you withdraw, you will only be paid for visits completed.

Visit	Compensation amount
Baseline survey, STI and HIV testing and YMHP or Treatment as Usual Session 1	$50 gift card ($25 gift card from Amazon.com, Target, or CVS for completing the computer based survey and $25 gift card from Target for completing first YMHP or Treatment as Usual session, HIV and STI tests).

If you are randomized to YMHP, Program Sessions 2-4	MetroCard ($5.50 value) and Food voucher ($7 value) for each of the three additional YMHP sessions. If the baseline and three additional YMHP sessions are complete you will receive an additional $20 gift card from Target.
Immediate Post-test assessment	$25 gift card from Target for computer based survey only
3-month assessment	$50 gift card from Target ($25 for completing the computer based survey and $25 for completing HIV and STI testing).
6-month assessment	$25 gift card from Target for computer based survey only
9-month assessment	$50 gift card from Target ($25 for completing the computer based survey and $25 for completing HIV and STI testing).

If you choose to participate in the one-on-one confidential interview with a member of our research staff you will also receive an additional $10 gift card from Target. 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. This is optional. This interview will be audio-recorded and take 30-45 minutes.

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.

NEW INFORMATION:

You will be notified about any new information regarding this study that may affect your willingness to participate in a timely manner.

CONFIDENTIALITY:

We will make our best efforts to maintain confidentiality of any information that is collected during this research study and that can identify you. We will disclose this information only with your permission or as required by law. We will protect your confidentiality in several ways. Your case will be assigned a code number, and all questionnaires and other materials generated by your participation in this study will be identified only by that code number. Any materials that match your code number to your name will be kept in a separate, locked file located at our research offices. The information obtained during this research will be kept confidential to the extent permitted by law and will be stored at our research offices for 3 years after the study is completed. Data that cannot be matched to you 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.

You will be asked to provide contact information which will help the YMHP researchers at BOOM!Health 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 CBO or Hunter College.

To protect your confidentiality during audio recording of the intervention sessions, no identifying information will be recorded on the audio files to connect you with the responses you provide to us. The audio recordings will be processed at Hunter College for quality assurance purposes. We will not keep personal identifiers with your recording. The audio recordings will be kept on a password-protected computer in a secure location available to the Hunter College research staff only. Audio recordings will be deleted 3 years after study completion.

Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances: if you reveal suicidal or homicidal feelings or that a child or elderly person is the victim of abuse, confidentiality will be waived and actions may be taken to protect you and/or others.

To help protect your confidentiality, a Certificate of Confidentiality has been obtained from NIH to help prevent 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.

The research team, authorized CUNY staff, authorized BOOM!Health, and government agencies that oversee this type of research may have access to research data and records in order to monitor the research. Research records provided to authorized, non-CUNY or non-research team individuals will not contain identifiable information about you. Publications and/or presentations that result from this study will not identify you by name.

Again, while every possible step will be taken to minimize the risk of a breach of confidentiality, if you have any concerns about any aspect of the study, you may refuse to continue with the study at any time, without penalty.

PARTICIPANTS' RIGHTS:

- Your participation in this research study is entirely voluntary. If you decide not to participate, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.
- You can decide to withdraw your consent and stop participating in the research at any time, without any penalty.

QUESTIONS, COMMENTS, OR CONCERNS:

If you have questions, comments, or concerns about the research, you can contact the study's Research Scientist, Demetria Cain, by phone 212-206-7919 or by email dcain@prideresearch.org, or the Principal Investigator, Dr. Tyrel Starks by phone at 212-206-7919.

If you have questions about your rights as a research participant or you have comments or concerns that you would like to discuss with someone other than the researchers, please call the CUNY Research Compliance Administrator at 646-664-8918 or by email at hrpp@cuny.edu. Alternatively, you can write to:

CUNY Office of the Vice Chancellor for Research
Attn: Research Compliance Administrator
205 East 42nd Street
New York, NY 10017

SIGNATURE OF PARTICIPANT:

If you agree to be audiotaped, please indicate this below.

_____ I agree to be audiotaped

_____ I do NOT agree to be audiotaped

If you agree to participate in this research study, please sign and date below. You will be given a copy of this consent form to keep.

Print Name: _____

Sign: _____ Date:_____

SIGNATURE OF INDIVIDUAL OBTAINING CONSENT:

Print Name: _____

Sign: _____ Date:_____