CONSENT

Prevention and Risk: Treatment with a new emphasis on Relationships (Project Partner)

NCT03396367

Sponsor: National Institute of Drug Abuse (NIDA)

Principal Investigator: Tyrel J. Starks, PhD
Hunter College,
New York, NY

Consent Version Date: **December 5, 2022**

THE CITY UNIVERSITY OF NEW YORK - Hunter College

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title of Research Study: PARTNER Project

Principal Investigator: Dr. Tyrel J. Starks
Associate Professor
Department of Psychology
Relationship Health Research Team
Hunter College, Room 1035 North
695 Park Avenue
New York, NY 10065

Research Sponsor: The National Institutes of Health

PURPOSE:

You are being asked to participate in a research study because we are interested in evaluating the efficacy of a drug use and HIV prevention intervention for young men in relationships. This form has important information about the reason for the study, what you will do, and the way we would like to use information about you if you choose to be in the study.

KEY INFORMATION:

• Your consent is being sought for participating in this research study.
• Your participation is voluntary.
• The purpose of the research is to help test an intervention to support the health of men in same-sex couples.
• The expected duration of your participation, if you choose to participate, is 12 months, involving a baseline visit, 4 one-hour sessions focusing on communication and health issues such as substance use and HIV risk, and 4 follow-up assessments at 3 months, 6 months, 9 months, and 12 months after the baseline visit.
• The reasonably foreseeable risks or discomforts of participating include the experience of talking about personal issues like health and relationships, and minimal physical discomfort associated with HIV and STI testing.
• An additional risk is a breach of confidentiality, as we are obligated to provide the New York Department of Health & Mental Hygiene with your name, date of birth, and phone number, if you test positive for gonorrhea or chlamydia through our STI test, or also if you are on PrEP and test positive for HIV via a confirmatory test. This is in accordance with New York City's Health Code Article 11.
• The benefits to you and to others that may be expected from the research include greater awareness of communication in relationships and information about health and HIV risk.

• In terms of appropriate alternative options for treatment that might be advantageous to you, there are no therapeutic alternatives available at this time.

PROCEDURES:
If you volunteer to participate in this research study, we will ask you to do the following:

Today

1. During the first remote session with study team member, you will be asked to present government-issued photo identification with your date of birth to the web camera. We will not make copies of this document and we will not be examining your legal name or legal sex. It will only be used to confirm that you are age 18 or older.

2. If you agree to be in this research, you will be emailed a link to complete an online survey before your next appointment with a study team member. This survey takes approximately one hour to complete and covers: demographic information; relationship characteristics; HIV-related knowledge, motivations, and testing behavior; as well as individual mental health and psychological functioning, substance use and sexual behavior.

3. After you complete the survey, Molecular Testing Labs (MTL) will mail you a box containing STI and HIV self-collection materials, with instructions on how to complete the collection. This box will also contain the mailing materials needed to return the STI, and HIV samples to MLT. RHRT staff will mail you a fingernail collection kit, containing instructions and a self-addressed, stamped envelope to return the sample. You will collect specimens for the following tests:

    a) Rectal swab to test for the presence of Gonorrhea and Chlamydia in the anus.
    b) Urine Sample to test for the presence of Gonorrhea and Chlamydia in the urinary tract.
    c) Fingernails sample from all 10 fingers. If there isn't enough nail, you will gather toenails instead of fingernails. We will be testing the use of illicit drugs, and if you are on PrEP, we will test your medication uptake as well. If, at the time of the appointment, you do not have enough nails to sample, you can mail them to RHRT once you have enough to collect.
    d) Blood via a finger prick to use blood spot collection for an HIV test. If the HIV dried blood spot collection is unsuccessful because of difficulties drawing sufficient blood from your finger, or if you choose not to provide a blood sample for this test, you may use an oral swab HIV test instead.

4. Once the bio-specimens have been received and analyzed by MLT, the research staff will refer to the results to confirm that the participant still meets the HIV-negative entry criteria for the study.

5. Once eligibility is confirmed, the research team will make an appointment for a Zoom appointment. During this appointment you will complete a timeline follow back interview (TLFB) with a staff member remotely which might take around 30 minutes.

6. Once you complete the TLFB, you will be randomly assigned (like flipping a coin) to the PARTNER intervention or education condition. The first session will happen right after you finish the baseline appointment today, or on another date and time. If you are assigned to the PARTNER intervention condition, you will remotely receive 4 counseling sessions in which you will be asked to talk about sex and drug use. If you are assigned to the education condition, you will meet remotely with a health educator to discuss the use of drugs and sexual risk behaviors. Both interventions require 4 sessions. You will complete one session today, or on another date if needed. The rest of the sessions can be completed once a week for the next three weeks. At the end of the 4th session, you will be asked a few questions about your experience in the study.

Following the 4 sessions, you will complete 4 follow-up appointments. Each appointment will last about 2 hours in total. These follow-ups will happen in the following order:

7. 3-Month Follow-Up. This happens 3 months from the Baseline appointment date. You will complete the following:
    A. Take an online survey as you did during your first remote study appointment. This survey takes approximately 30 minutes to complete and covers: demographic information; relationship characteristics; HIV-related knowledge, motivations, and testing behavior; as well as individual mental health and psychological functioning, substance use and sexual behavior.
    B. After you complete the survey, you will complete a timeline follow back interview with a staff member which might take around 30 minutes.
    C. Next MTL will mail you a collection kit to provide biological specimens for the following tests. You will be collecting your own samples. MTL will remind you of the procedures with an enclosed brochure.
        a. Fingernails sample from all 10 fingers and possibly toenails in case the fingernail sample is not enough. We will be testing the use of illicit drugs, and if you are on PrEP, we will test your medication uptake as well. If, at the time of the appointment, you do not have enough nails to sample, you can mail them to RHRT once you have enough to collect.
        b. If you are currently taking PrEP, there will be a dried blood spot card in the specimen collection box from MTL which we will use to examine your PrEP adherence.

8. 6-Month Follow-Up. This happens 6 months from the Baseline appointment date. You will complete the following:

A. Take an online survey as you did during your first remote study appointment. This survey takes approximately 30 minutes to complete and covers: demographic information; relationship characteristics; HIV-related knowledge, motivations, and testing behavior; as well as individual mental health and psychological functioning, substance use and sexual behavior.
B. After you complete the survey, you will complete a timeline follow back interview with a staff member which might take around 30 minutes.
C. Next you will be mailed a box containing STI and HIV self-collection materials, with instructions on how to complete the collection, from Molecular Testing Labs (MTL). This box will also contain the mailing materials needed to return the STI and HIV samples to MLT. RHRT staff will mail you a fingernail collection kit, containing instructions and a self-addressed, stamped envelope to return the sample. You will collect specimens for the following tests:
    a. Rectal swab to test for the presence of Gonorrhea and Chlamydia presence in the anus
    b. Urine Sample to test for the presence of Gonorrhea and Chlamydia in the urinary tract.
    c. Fingernails sample from all 10 fingers. If there isn't enough nail, we'll gather toenails instead of fingernails. We will be testing the use of illicit drugs, and if you are on PrEP, we will test your medication uptake as well. If, at the time of the appointment, you do not have enough nails to sample, you can mail them to MTL once you have enough to collect.
    d. Blood via a finger prick for blood spot collection for the HIV test. If the HIV dried blood spot collection is unsuccessful because of difficulties drawing sufficient blood from your finger, or if you choose not to provide a blood sample for this test, you may use an oral swab HIV test instead.

9. About 9 months from today, you will be asked to complete another appointment. You will complete the following:
    A. Take an online survey as you did during your first remote study visit. This survey takes approximately 30 minutes to complete and covers: demographic information; relationship characteristics; HIV-related knowledge, motivations, and testing behavior; as well as individual mental health and psychological functioning, substance use and sexual behavior.
    B. After you complete the survey, you will complete a timeline follow back interview with a staff member which might take around 30 minutes.
    C. Next MTL will mail you a collection kit to provide biological specimens for the following tests. Again, MTL will enclose a brochure to guide you through the self-collection process.

a. Fingernails sample from all 10 fingers. If there isn't enough nail, we'll gather toenails instead of fingernails We will be testing the use of illicit drugs, and if you are on PrEP, we will test your medication uptake as well. If, at the time of the appointment, you do not have enough nails to sample, you canmail them to RHRTonce you have enough to collect.
b. If you are currently taking PrEP, there will be a dried blood spot card in the specimen collection box from MTL which we will use to examine your PrEP adherence.

9. Lastly at about 12 months from today, you will complete your final follow-up appointment. You will complete the following:

A. Take an online survey as you did during your first remote study visit. This survey takes approximately 30 minutes to complete and covers: demographic information; relationship characteristics; HIV-related knowledge, motivations, and testing behavior; as well as individual mental health and psychological functioning, substance use and sexual behavior.
B. After you complete the survey, you will complete a timeline follow back interview with a staff member which might take around 30 minutes.
C. Next you will be mailed a box containing STI and HIV self-collection materials, with instructions on how to complete the collection, from Molecular Testing Labs (MTL). This box will also contain the mailing materials needed to return the STI and HIV samples to MLT. RHRT staff will mail you a fingernail collection kit, containing instructions and a self-addressed, stamped envelope to return the sample. You will collect specimens for the following tests:
    a. Rectal swab to test for the presence of Gonorrhea and Chlamydia in the anus.
    b. Urine Sample to test for the presence of Gonorrhea and Chlamydia in the urinary tract.
    c. Fingernails sample from all 10 fingers. If there isn't enough nail, we'll gather toenails instead of fingernails. We will be testing the use of illicit drugs, and if you are on PrEP, we will test your medication uptake as well. If, at the time of the appointment, you do not have enough nails to sample, you can mail them to RHRT once you have enough to collect.
    d. Blood via a finger prick for blood spot collection for the HIV test. If the HIV dried blood spot collection is unsuccessful because of difficulties drawing sufficient blood from your finger, or if you choose not to provide a blood sample for this test, you may use an oral swab HIV test instead.
D. Finally, you will be interviewed one-on-one by the Research Assistant who will ask you 10-15 questions about your experiences in the study and any suggestions you might have about the intervention. This interview will also

be audio-recorded so that your answers can be typed out in full (i.e., transcribed). No identifying information will be included in the transcription. At any time during the interview, you have the right to ask for the recording to be paused if you wish.

If your HIV test results are invalid you'll need to do a repeat test. You can opt to take it remotely or with your own health care provider. If you don't have a provider, we have partnerships with community health centers to provide this test for you.

If your test result indicates that you need confirmatory testing, we can help you find a provider in your state who will complete any additional diagnostic testing required and set up follow-up medical services as needed. Confirmatory testing will include a discussion of HIV testing result reporting to your state's Department of Health and notifying any additional sex or needle-sharing partners (where applicable) of possible exposure to HIV.

REPORTING OF HIV TEST RESULTS: Most states require that HIV tests conducted at health clinics or in the context of research are reported to their Department of Health. If you complete confirmatory testing and test positive, your name, date of birth, and phone number may be given to your state's department of health to help with their tracking of infection rates. Some states also provide follow-up services to insure that people diagnosed with HIV receive essential medical care.

RECEIVING YOUR STI/HIV RESULTS

Rectal STIs, chlamydia and gonorrhea, are being tested using self-collection kits. When your self-collection kit is mail to you, your name, date of birth, address, email, and phone number will be provided to Molecular Testing Labs. Samples will be sent for analysis to Molecular Testing Labs. All test results will be conveyed to you through a secure link from the Relationship Health Research Team along with local resources. In the event of a positive HIV test, the Principal Investigator, Dr. Tyrel Starks or a member of his clinical response team, will call you to deliver the result. RHRT clinical team will attempt to call you three times over a 2 week period. If the clinical team cannot reach you, the Relationship Health Research Team will mail you the results. You will have the option to speak to members of our research staff to help identify locations for treatment.

Some state laws require that positive STI results are reported to the Department of Health. In accordance with state-based reporting laws, certain diseases and conditions (which include gonorrhea and chlamydia) will be reported to your state's Department of Health immediately by Molecular Testing Labs. If you test positive for either gonorrhea or chlamydia, Molecular Testing Labs will provide your name, date of birth, address, email, and phone number to your state's Department of Health as required under your state's laws. This procedure is consistent

with standard procedures at any medical clinic. As a result, local officials in some states may reach out to you to provide linkage to care.

TIME COMMITMENT:
Your participation in this research study is expected to last for a total of approximately 12 months.

POSSIBLE RISKS OR DISCOMFORTS:
Your participation in this study may involve the following risks:

- There is a chance that you may feel emotional or upset when answering some of the survey questions. Tell the study staff at any time if you wish to take a break or stop the survey.
- You may be uncomfortable with some of the topics discussed during the HIV testing session. If you are uncomfortable, you are free to not respond to any questions asked.
- If you agree to HIV testing, the process will involve a finger prick to draw blood which may cause temporary discomfort, and possible infection. On rare occasions, some participants may pass out at the sight of blood.
- As mentioned, you could test HIV-positive during the course of the study. We have a comprehensive care plan in place with staff at Callen-Lorde, Mt. Sinai hospital and GMHC's Prevention Center.
- If you agree to Fingernail Collection, the process may involve a nail clipper to self-collect fingernails from all 10 fingers and/or toes, this process which may cause temporary discomfort.
- If you agree to STI testing, the process may involve:
    - For Urethral test: to urinate in a specimen cup.
    - For Rectal test: to insert a Q-tip swab in the rectum to self-collect an anal sample which may cause temporary discomfort.
    - While both a project coordinator and a project director here at the Relationship Health Research Team will check and double-check the correct data entry of these STI results, human error is always a possibility. Our quality assurance process aims to minimize this possibility.
    - There is also a risk of incorrect test results being generated as a consequence of participant error in self-administering the STI tests. Our process for explaining the tests to you before you administer them aims to minimize this possibility.
    - If an error is made and a positive test result is not correctly identified, there is a risk of potentially infecting a sexual partner. Our processes for ensuring accuracy aim to minimize this possibility.
- An additional risk is a breach of confidentiality, as we are obligated to provide the New York Department of Health & Mental Hygiene with your name, date of birth, and phone number, if you test positive for gonorrhea or chlamydia through the self-collection STI test, or also if you are on PrEP and test positive for HIV via a confirmatory test. This is in accordance with New York City's Health Code Article 11.

POTENTIAL BENEFITS:

As a possible benefit, the program may provide you the opportunity to discuss important issues in your relationship that may not have been previously discussed, such as dating history, thoughts on sexual agreements in the relationship, and HIV/STI testing. The program will also offer you the opportunity to build relationships skills to talk with your partner, including communication skills. In addition, you will be offered free, voluntary HIV and STI testing. Your participation may also help other young people in the future as we design healthy relationships programs to promote healthy sexual behaviors, specifically for same-sex couples.

PAYMENT FOR PARTICIPATION:

Participation in this study will involve no cost to you. For participating in this study, you may receive up to $380. If you withdraw from the study, you will be paid only for the portions that you completed. No subsequent payment will be given. The payment schedule is:

$50 for completing all baseline activities
($20 for the surveys. $20 for the Timeline Follow Back. $10 for Nail samples for drug testing, STI testing Rectal and Urethral, and HIV testing)
$20 for each completed session (up to $80 total);
$60 for completing a 3-Month Follow-Up Assessment
($20 for the surveys. $20 for the Timeline Follow Back. $20 for Nail samples for drug testing and dried blood spot testing – only for those on PrEP)
$60 for completing a 6-Month Follow-Up Assessment;
($20 for the surveys. $20 for the Timeline Follow Back. $20 for Nail samples for drug testing, STI testing Rectal and Urethral, and HIV testing)
$80 for completing a 9-Month Follow-Up Assessment
($30 for the surveys. $30 for the Timeline Follow Back. $20 for Nail samples for drug testing and dried blood spot testing – only for those on PrEP)
$100 for completing a 12-Month Follow-Up Assessment;
($30 for the surveys. $30 for the Timeline Follow Back. $30 for Nail samples for drug testing, STI testing Rectal and Urethral, and HIV testing, and $10 for the interview)

You will receive an Amazon.com gift card for the assessment components that are delivered online.

SETTING-UP APPOINTMENTS

We will send you an email at the address you provide. We can send you a text message (also known as SMS or texts). If you opt to get text messages, message and data rates may apply. Our research center or CUNY will not cover the costs of text messages or data used. Check with your cellphone carrier if you have any questions about your text message plan.

You will be asked at the end of this form to let us know if you want receive text messages or not. If you say that you want to receive text messages now, but decide that you no longer want to receive text messages, please email projectpartner@prideresearch.org to let us know. Also, if you decide you do not want to receive text messages at this time, but you change your mind in the future, please email projectpartner@prideresearch.org to let us know.

The decision you make on receiving or not receiving text messages will not impact your ability to join this study.

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. There is always a slight risk that this may be broken, but your confidentiality will be guarded in several ways.

More specifically, your case will be assigned a code number, and your survey 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. Some confidential information will be collected such as your birthdate, zip code, and HIV status. However, this information will not be stored with other identifiable information such as your name, phone number or email address. The information obtained during this study will be kept confidential. Please note that you will not be able review or edit your survey responses one you submit them. You will also not be able to view or edit your data or recordings. The data related to this study will be stored on a password protected computer that is connected to a secure server.

There are certain legal limits to confidentiality. If you reveal suicidal or homicidal thoughts or feelings or reveal that a child or elderly person has been or may be the victim of abuse, confidentiality may be waived and actions may be taken to protect you or others.
The research team, authorized CUNY staff, 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 individuals will not contain your name, phone number, or email address. This data, which cannot be linked to you, may also be shared with other researchers outside of CUNY, for which appropriate permissions will be sought. If non-CUNY individuals request our data, there will be special permission from the CUNY 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 contain your name, phone number, or email.

CERTIFICATE OF CONFIDENTIALITY:

To help us protect your privacy, we have a Certificate of Confidentiality from the National Institutes of Health. 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 researchers will use the Certificate to resist any demands for information that would identify you,

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be

disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). 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, medical care provider, 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 be used to prevent disclosure to state or local authorities of information indicating you present an imminent danger to yourself or others.

AUDIO RECORDING:

As part of this project, an audio recording will be made of you during your participation in this research project. Only your study identification number will appear on the audio file. Audio files will be stored on password-protected computers in a locked office and only Dr. Starks and the research team will have access to them. The audio records will be transcribed verbatim. In the event that you accidently reveal any personally-identifiable information (e.g., your name) during the interview, this will be removed in the transcription. The audio recordings will be kept for three years after the study is completed, at which point they will be destroyed.

By signing this form and indicating your consent to participate, you are agreeing to permit the recording of sessions.

PARTICIPANT'S 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.
- If you end your participation, you will still be entitled to the incentives that are owed to you up until the point that you withdrew. You will not receive subsequent incentives.

If you decide to leave the study, please contact the Principal Investigator, Dr. Tyrel Starks, to inform him 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 objectives of the study. All data will be kept securely stored and confidential, as detailed above, and analyses and study reports will not in any way reveal the identity of participants. 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.

OTHER INFORMATION:

We may end your participation for a number of reasons:

1. During the course of the session or assessment it becomes clear that you do not meet study eligibility criteria,

2. Physical or psychological problems arise which would interfere with the study,
3. If you attend a meeting drunk or high,
4. If we feel that it is in the best interests of your health, and/or
5. 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. You may still be invited to complete the follow-up survey.

QUESTIONS, COMMENTS OR CONCERNS:

If you have any questions, comments or concerns about the research, you can contact Dr. Tyrel Starks at 212-206-7919 or projectpartner@prideresearch.org.
If you have questions about your rights as a volunteer or you are not satisfied with Dr. Starks' responses to your questions, you can contact the CUNY Research Compliance Administrator at 646-664-8918 or by email at hrpp@cuny.edu. Alternatively, you may write to:
CUNY Office of the Vice Chancellor for Research
Attn: Research Compliance Administrator
205 East 42nd Street
New York, NY 10017

Please let us know if you are still willing to receive text messages. Remember that you can always change your mind.

- Yes, I am willing to receive text messages.
- No, I do not want to receive text messages.

STATEMENT OF CONSENT/SIGNATURE OF PARTICIPANT:

I have read the above description of this research and I understand it. I have been informed of the risks and benefits involved, and all my questions have been answered to my satisfaction. Furthermore, I have been assured that any future questions that I may have will also be answered by the Principal Investigator of the research study. I voluntarily agree to participate in this study.

If you agree to participate in this research study, please verbally indicate your consent to the project personnel. You will be given a copy of this consent form to keep.