NYSPI IRB Approved
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12/14/2020 -> 11/12/2021

Young Adult Informed Consent for HIV and/or STI Testing
Health and Justice: A Continuum of Care for HIV and SU for
Justice-Involved Young Adults (Phase 2)
(Katherine Elkington, PhD, 646-774-6965)

CONSENT SUMMARY PAGE

Overview
Below is a summary of the study that you are asked to participate in. This outline is meant to be a guide for you to use while considering the study and reading the consent form. It is not meant to replace the consent form, which you will have to sign if you decide to participate in the study. The consent form contains detailed information about the study and about the risks which you will need to consider before making your decision. Read the consent form carefully and discuss it with others before deciding to take part. And remember that, even if you agree to participate, you can change your mind at any time

Voluntary
As with all research, this is a voluntary study, and you do not have to participate if you do not want to. Also, you may stop participating at any time.

Procedures
- You will be offered an opportunity for an HIV and STI test – it is voluntary.

Risks and Inconveniences
This study includes some risks and discomforts (please refer to the consent form for further details and explanations of these risks). These include loss of confidentiality related to your responses and possible discomfort because of the types of questions we ask.

Benefits
This research study is not meant to benefit you directly.

Questions
You may contact the study principal investigator, Dr. Kate Elkington at 646-774-6965 at with any questions.

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Purpose of the Study: Sexual health is an important part of the Link2CARE study. We would like to do a rapid Human Immunodeficiency Virus (HIV) test and collect your urine to test for any sexually transmitted infections (STI).

Voluntary: Participation in the HIV and STI testing is voluntary. You do not have to participate in the HIV and STI testing in order to participate in the study. The alternative to not participating is simply to not take part, you can still participate in all other parts of the study. If you decide not to participate, you will not lose any study compensation to which you are otherwise entitled and you will still receive all services as usual through Brooklyn Justice Initiatives (BJI) and your terms at BJI will not change. Study participation will not affect anything related to your status at BJI, either positively or negatively.

Procedures: During your appointment with our Health Coach, we would like to test for HIV using the OraQuick® ADVANCE™ Rapid HIV-1/2 Antibody Test. To use the OraQuick HIV Test, one simply swabs the gums of the person to be tested. This test is already approved by the Food and Drug Administration (FDA) for use in doctors' offices and testing facilities. We will read the test in a confidential location at BJI and tell you the results within 20-30 minutes of taking the test. If your HIV test result is reactive or if your STI test result is positive, we will discuss with you what that means and will offer counseling and help you schedule an appointment for confirmatory testing. Positive HIV test results, along with your name, will be reported to the Department of Health following New York State approved guidelines to guarantee confidentiality.

The STI testing requires a small amount of urine. The urine test will be collected and processed using a Gen-probe Aptima Urine Specimen Collection Kit for Male and Female Urine Specimens. The testing kits are provided and the urinalysis is performed by the New York City Department of Health and Mental Hygiene. You will receive your results within 14 days. If you test positive for an STI, you will be contacted by a health coach within 48 hours of us receiving the results. They will help you to schedule an appointment at a clinic for treatment. Positive STI results, along with your name, will be reported to the NYS Department of Health following New York State approved guidelines to guarantee confidentiality.

We will offer you the option of being re-tested for HIV and STIs when we interview you 6 months from now, and again 12 months from now.

Risks and Inconveniences: It is possible that you may feel anxious about being tested for HIV and STIs. If this happens, you can choose to withdraw from testing at any time. You may also feel distressed if testing results are positive, not knowing what to do next. In this case, we will talk with you about next steps and what can be done, and we will make sure we schedule an appointment at a nearby clinic.

Benefits: Participation in this study may be of no direct benefit to you. However, we expect that by participating, you will contribute to a better understanding of your own sexual health because you will have the opportunity to reflect on your sexual practices and you will be tested for HIV and STIs. If the results of the HIV test are positive, you may benefit from discussion with the study's staff, who are trained to assist someone prepare for and manage the results of an HIV test. You will also be

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offered referrals to professionals who can give you advice about further medical evaluation, treatment and support services, in addition to any other referrals they deem appropriate.

Confidentiality: All testing papers and records will be stored in a locked cabinet. Records will only be available to research staff and to Federal, State and Institutional regulatory personnel (who may review records as part of routine audits). The results will not be part of your record at BJI and will not be shared with any of the BJI staff or with the Court. The clinic that conducts the confirmatory HIV test and the lab that analyzes your urine for STIs are required to report positive results to the Health Department. In the case of positive HIV results, your doctor will also discuss partner notification with you. Reporting is done through a secure system designed specifically for this purpose. The Department of Health can only use this information to understand these diseases and cannot disclose individual names. We have received a Certificate of Confidentiality issued by the Federal Government for this study. With this Certificate, the researchers cannot be forced to release any information that identifies you without your written consent. **Your private information will not be used for any future research studies or distributed to another investigator for future research studies.**

Study Compensation: There is no compensation for taking the HIV or STI test.

In Case of Injury: If you believe that you have sustained an injury as a result of participating in this research study, you may contact the Principal Investigator, Dr. Kate Elkington at 646-774-6965 so that you can review the matter and identify the medical resources that may be available to you. The New York State Psychiatric Institute does not provide compensation or payment for treatment of research-related injuries. However, you should be aware that participation in this research does not waive any of your legal rights to seek such compensation through the courts.

Questions: The study staff will answer to the best of her/his ability any questions you may have, now or in the future, about the study. If you have any further questions about this project or testing, please call Dr. Kate Elkington at 646-774-6965.

If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). (An IRB is a committee that protects the rights of participants in research studies). You may call the IRB Main Office at (646)774-7155 during regular office hours.

Documentation of Consent:

- ☐ I voluntarily agree to be tested for HIV
- ☐ I voluntarily agree to be tested for STIs

Participant's name (print):_____

Participant's signature:_____

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Person Designated to Obtain Consent:

I have discussed the proposed research with this participant including the risks, benefits, and alternatives to participation (including the alternative of not participating in the research). The participant has had an opportunity to ask questions, and in my opinion, is freely consenting to participate in this research.

Print name:_____

Signature: _____

Date:_____

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