Consent Form and HIPAA Authorization

Please complete the form below.

Thank you!

Columbia University Consent Form and HIPAA Authorization

Protocol Information
Attached to Protocol: IRB-AAU1706

Principal Investigator: Rebecca Schnall (rb897)

IRB Protocol Title: mLab App Plus: A randomized controlled trial of an mHealth intervention for increasing access to HIV and syphilis testing and care among young men (NCT06059443)

General Information
Consent Number: CF-AABW2050

Participation Duration: 3 months

Anticipated Number of Subjects: 100

Research Purpose: The purpose of this study is to learn about HIV and syphilis testing and linkage to care among young adults.

Contacts

Contact	Title	Contact Information	
Rebecca Schnall	Principal Investigator	Phone: 212-342-6886	Email: rb897@cumc.columbia.edu

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Information on Research

Key Information

The purpose of this research study is to learn about HIV and syphilis testing and linkage to care among young adults. We are conducting a study to assess the feasibility (ability) of using the DPP HIV-Syphilis test as a self-test to improve uptake and access to sexually transmitted infection (STI) testing among young adults. Subjects will be randomized (randomly assigned, like flipping a coin) to one of two arms: mLab App Plus or Standard of Care. The mLab App Plus is not approved by the FDA for this use and it is investigational only, thus participants should not rely on the app's interpretation of the test results. DPP HIV-Syphilis tests are not yet FDA approved as self-tests. The time frame for your involvement in the study is 3 months. The introduction section below provides details about the study. Risks for the study include discomfort with some of the survey questions, with the provided HIV prevention information, or knowing that, although unlikely, there is a potential risk for loss of confidentiality. You might feel emotionally upset or distressed by your HIV and syphilis testing results. Details of all the known risks are listed in the Risks section. By participating in this study, you may benefit by having access to in-home HIV and syphilis tests. Detailed information about benefits can be found in the Benefits section. It is your choice if you want to be in this study. The alternative is to not participate. If you decide that you do want to participate in the study, it should be because you really want to volunteer. You can choose to withdraw at any time during the study. If you choose not to volunteer you will not lost any services, benefits, or rights you would normally have. If you are interested in learning more about this study, please read the details below.

The purpose of this form is to give you information to help you decide if you want to take part in a research study. This consent and HIPAA authorization form includes information about:

- why the study is being done;
- the things you will be asked to do if you are in the study;
- any known risks involved;
- any potential benefit;
- options, other than taking part in this study, that you have; and
- the way your health information will be used and shared for research purposes.

A member of the study team will discuss the study with you. If at any time you have questions about the study, please ask a member of the study team. Take all the time you need to decide whether you want to take part in this research study.

The purpose of this research is described below in the 'What is Involved in This Study?' section of this consent form. This consent and HIPAA authorization form is written to address a research subject.

What Is Involved in this Study?

We are conducting a study to assess the feasibility (ability) of using the DPP HIV-Syphilis test as a self-test to improve uptake and access to sexually transmitted infection (STI) testing among young adults. If you agree to be in the study, the following will happen:

1. You will be randomized (randomly assigned, like flipping a coin) to one of two arms: mLab App Plus or Standard of Care.

2. You will receive standard-of-care HIV/STI testing-related risk reduction counseling, a box of condoms, PrEP assessment, and referral information for clinics that provide PrEP.

3. As a participant in this study, you will complete an online survey at our clinic in Washington Heights for your first visit.

4. For your first visit, ONE of the following will occur, depending on which arm you are randomized to:

a. If you are randomized to mLab App Plus, you will receive the following:

1. mLab App Plus - A mobile app on your phone that you will access using a login name and password provided to you by the study team member. The app will provide HIV and STI prevention information, push notification reminders for testing, step-by-step instructions for using the DPP® HIV-Syphilis tests, and an image upload function to help you interpret your test results and send them to the study team. By using the app, we will ask you to test the app's ability to interpret the results of the DPP® HIVSyphilis tests. Upon receiving a test result, a study team member will meet with you at the clinic, immediately after you have completed your DPP® HIV-Syphilis test. They will discuss with you what your test result means and what it does NOT mean. In the event of a positive test result, the study team member will offer you support and help you set up an appointment at our clinic for confirmatory testing. All information that you provide within the app will be stored on a secured server. The mLab App Plus is not approved by the FDA for this use and it is investigational only, thus participants should not rely on the app’s interpretation of the test results.

2. A DPP HIV-Syphilis test kit. You will receive a DPP HIV-Syphilis test kit at your baseline appointment. You will be self-administering the test at our clinic in Washington Heights in the presence of a medical provider. In order to perform the test, you will be given sampling materials such as sterile lancets (small, pointed instrument that is used to prick a finger for a blood test), antiseptic wipes and bandages at the clinic. Additionally, you will be given a DPP Micro Reader which is a device that you will be instructed to attach to the test to run the test results. If you feel uncomfortable or unable to perform the test on yourself, you may ask the clinician to administer it for you. DPP HIV-Syphilis tests are not yet FDA approved as self-tests.

3. A study information card listing the study teams' contact information.

4. After your visit, you will be sent an email or text with links to mobile-optimized online prevention information, including PrEP and HIV testing information.

5. The first study visit will take about 2-3 hours.

OR

b. If you are randomized to the Standard of Care, you will receive the following:

1. A study information card listing the study teams' contact information.

2. After your first visit, you will be sent an email or text with links to mobile-optimized online prevention information, including PrEP and HIV testing information.

3. The first study visit will take about 1-2 hours.

5. Three months after your initial visit, you will complete another survey. mLab App Plus ONLY: you will complete another DPP HIV-Syphilis test using mLab App Plus in the presence of a provider at your 3-month follow-up appointment.

6. You may also receive text messages or phone calls from the study team if you choose this method for communication. mLab App Plus ONLY: you may receive messages from the study team through the app. Text messages will not disclose study participation nor HIV/Syphilis status.

For further clarity of the events that will occur at your study appointments, please refer to the chart below.

Schedule of Events

	mLab App Plus Group		Standard of Care Group	
	Baseline	3-Months	Baseline	3-Months
Standard-of-Care Counseling*	X		X	
Online Survey	X	X	X	X
mLab App Plus	X			
DPP HIV-Syphilis Test	X	X		

*Receipt of standard-of-care HIV/STI testing-related risk reducation counseling, box of condoms, PrEP assessment, and referral information for clinics that provide PrEP.

Technical Difficulties

If you have any technical difficulties using the mLab App Plus or the DPP HIV-Syphilis tests, please contact our study staff at:

Office Phone: 212-305-8198

Permission for Future Contact

The researchers may want to contact you in the future. This study has the potential for revealing information about mobile apps for HIV prevention and treatment. We would contact you only once to solicit your participation in any research associated with the current study.

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1) Please indicate below to show whether or not you give permission for future contact.

- ◯ I give permission to be contacted in the future for research purposes and for information relating to this study.
- ◯ I DO NOT give permission to be contacted in the future for research purposes and for information relating to this study.

Risks
General Risks:

1. There may be risks or discomforts if you take part in this study. These include feeling uncomfortable with the prevention information that is provided to you and feeling discomfort completing some questions in our survey. A risk of taking part in this study is the possibility of a loss of confidentiality or privacy, including that associated with the app on your phone. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy. Their plans for keeping your information private are described in the Privacy section of this consent form.

Risks Specific to the Use of DPP HIV-Syphilis Test:

1. DPP HIV-Syphilis tests are not yet FDA approved as self-tests. In order to mitigate risks associated with using a DPP HIV-Syphilis test as a self-test, a qualified clinician will be present as you are completing the test, however, this does not completely remove the risk of using the test as a self-test. If you feel uncomforable or unable to perform the DPP HIV-Syphilis test as a self-test, you may ask the clinician to administer it for you.

2. Subjects must follow package instructions on the DPP HIV-Syphilis test and always read the test results from the DPP HIV-Syphilis Micro Reader display screen following the test kit instructions themselves to ensure accurate interpretation given that the accuracy of the mLab App Plus application has not been proven. The supervising clinician must also read the test results from the test itself. Confirmatory HIV/Syphilis testing is still needed.

3. You may mistakenly believe that a negative result of the DPP HIV-Syphilis Tests means that you are not infected with HIV/Syphilis. There is a chance that the test does not detect an HIV/Syphilis infection. To offset this risk, you will be repeatedly told that a negative result in the DPP HIV-Syphilis test does not mean that you are not HIV/Syphilis infected, since infections that occurred within the prior three months may not be detected by the test, and that condoms should still be worn to avoid the risk of HIV and other STIs.

4. You may experience distress if you get a positive result in the DPP HIV-Syphilis test. If at any point during your participation in this study you request a referral for a confirmatory test, we will refer you to an HIV/STI clinic for a confirmatory test and referrals for treatment and care if needed, including psychological assistance. We will assist you in scheduling an appointment for a first consultation.

5. There is a risk of receiving a false positive test result, meaning you have tested HIV and/or syphilis positive, but are in fact HIV and/or syphilis negative. You will be instructed on the limitations of the DPP® HIV-Syphilis Test, including that false positive results have occurred, which again stresses the need for confirmatory testing since results may change.

Limitations of the DPP HIV-Syphilis Test:

A potential risk of the study is that you might mistakenly believe that the test kit protects you against HIV and/or other STIs. It is important that you know that self-tests will not protect you against HIV or other sexually transmitted diseases or infections, and you must use protection such as condoms when engaging in sexual intercourse if you want to avoid infection. HIV/Syphilis testing also does not include testing for STIs. A positive result from the DPP HIV-Syphilis Test generally indicates that HIV antibodies have been detected in your body. There is a small risk that a positive result is a mistake. Fewer than 1 in 100 people who get tested may receive an incorrect result. Therefore, if you test positive, a second test is needed to confirm the result. If you receive an HIV positive result while testing during this study, we will provide you with confirmatory testing referrals. A negative result in the DPP HIV-Syphilis test generally means that HIV/Syphilis has not been detected in your body and that you are HIV/Syphilis uninfected. A negative result could also mean that you may have gotten HIV/Syphilis too recently for the test to detect it. Confirmatory HIV/Syphilis testing referrals will be made available to all subjects.

Risks Specific to the Use of the mLab App Plus:

1. The mLab App Plus is not FDA-approved for interpreting the DPP HIV-Syphilis tests. Results from the mLab App Plus are investigational therefore the study team's interpreation of the results from the DPP HIV-Syphilis test are the more appropriate to refer to.

2. There may be false positive results related to the performance of the mLab App Plus, integration with REDCap and potential problems with the usability of the overall system.

3. There may be false negative or false positive results caused by issues with the imaging algorithm (e.g. lighting, geometries, and appropriately set processing thresholds) of the app.

If you are injured:

Taking part in this research study may result in injury or harm to you. In the event of an injury resulting from your participation in this research study, you should seek appropriate medical care and inform the Principal Investigator. In the event of an emergency, you should go to an emergency room.

If you are injured or harmed as a result of participating in the research study and receive medical care through The New York and Presbyterian Hospital, a Columbia doctor, or any other health provider, you will be sent a bill for whatever medical care you receive. All or part of your bill may be paid by your health insurance.

Columbia University and The New York and Presbyterian Hospital are not offering to provide you treatment after the end of the treatment or to pay you for pain, worry, lost income, the cost of your medical care or non-medical care costs that might occur as a result of your taking part in this treatment. However, when you sign this form, you keep all your legal rights.

Columbia University Irving Medical Center, The New York and Presbyterian Hospital, and Vanderbilt University are not offering compensation in the event of an injury related to mLab App Plus.

Benefits

We do not know if you will get any health benefits by taking part in this research study.

If you are randomized to the group that gets the HIV/Syphilis test done, you may benefit from reflecting on sexual practices, discussing sexual-risk behavior, and by having an HIV/Syphilis test. If the results of the HIV/Syphilis test come back positive, you may benefit from having the chanceto discuss the results with study staff, trained in pre- and post-test counseling. You will also be offered a confirmatorytest referral to professionals who can give you advice about medical care and treatment, and other support services.

Alternative Procedures

The alternative is not to participate. You are free to refuse to participate or to withdraw from this research at any time.

Confidentiality

To help us protect your privacy, we received a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, we cannot be forced to provide information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. We will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate of Confidentiality does not stop you or a member of your family from telling others about yourself or your involvement in this research. If an insurer, employer, or other person gets your written consent to receive research information, then we cannot use the Certificate to withhold that information.

The Certificate cannot be used to resist a demand for information from representatives of the United States Government that is used for auditing or evaluation of projects they are responsible for overseeing or for information that must be provided in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should also know that this Certificate does not protect you from our responsibility to report certain communicable diseases, suspected child abuse, or danger of physical or mental harm, to appropriate agencies or authorities.

Use and Sharing of the Data That Identify You: HIPAA Authorization

By signing this form, you authorize Columbia University Irving Medical Center, The New York and Presbyterian Hospital, Dr. Rebecca Schnall and her staff to use and disclose your Protected Health Information in connection with this research study as further described in this authorization. This authorization is designed to comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations; namely, the Privacy Rule.

What is Protected Health Information?

Protected Health Information or "PHI" are records that identify you which are created or collected in the course of this treatment plan. This PHI may include, but is not limited to, your name, address, telephone number, date of birth, government-issued identification number, and medical records and charts, including the results of all tests and procedures performed during this research study.

For what purposes can your PHI be used or disclosed by the doctor or staff?

Your PHI may be used or disclosed by the doctor or staff in order to conduct this treatment plan, as necessary for your treatment plan-related treatment or payment for such treatment, to allow the Institution to conduct its normal business operations, and to ensure that information relating to this treatment plan is available to the parties that need it for treatment purposes. Another type of disclosure may be to regulatory authorities (e.g., the U.S. Food and Drug Administration [FDA]), Institutional Review Boards or other persons required by law to properly conduct and monitor this treatment plan, including those verifying the proper collection of data. PHI may also be used by the doctor or staff to determine your health, vital status or contact information should you withdraw from treatment or are lost to follow-up.

Any information collected during this study that can identify you by name will be kept confidential. We will do everything we can to keep your data secure, however, complete confidentiality cannot be promised. Despite all of our efforts, unanticipated problems, such as a stolen computer may occur, although it is highly unlikely.

Access to your health information is required to be part of this study. If you choose to take part in this study, you are giving us authorization (i.e. your permission) to use the protected health information and information collected during the research that can identify you. The health information that we may collect and use for this research may include medical history that may be considered sensitive. This will include information relating to HIV. Your participation in this research study will be documented in your electronic medical record and can be viewed by authorized personnel from Columbia University Irving Medical Center, Weill Cornell Medical Center and The New York and Presbyterian Hospital and its affiliated institutions, because these institutions share the electronic medical record system. Study monitors and others who provide oversight of the study may also need to access this record.

Your questionnaire responses and interview answers will be assigned a code number, and separated from your name or any other information that could identify you. The research file that links your name to the code number will be kept in an encrypted data file on a password-protected computer and only the investigator and study staff will have access to the file.

Your participation in this research study will be documented in your electronic medical record. This record can be viewed by authorized personnel from Columbia University Irving Medical Center, Weill Cornell Medical Center and New York-Presbyterian Hospital and its affiliated institutions, because these institutions share the electronic medical record system. Study monitors and others who provide oversight of the study may also need to access this record.

Results of your research tests, including scans, (will) (will not) be returned to you and they will not be documented in the electronic medical record. Research tests are those that are conducted solely for research and would not be conducted if you were not in this study. Research results, including individual research results, will not be disclosed to subjects,

Vanderbilt University will have access to all data collected through the mLab App Plus which includes but is not limited to the results of the DPP® HIV-Syphilis test that you report through the app, the images that you upload through the app and the interpretation of the image results.

The following individuals and/or agencies will be able to look at and copy your research records:

The investigator, Columbia University Irving Medical Center study staff and other medical professionals who may be evaluating the study Authorities from Columbia University including the Institutional Review Board ('IRB') The Office of Human Research Protections ('OHRP') The United States Food and Drug Administration ('FDA') Our Sponsor, the National Institute of Health ('NIH') Vanderbilt University Your authorization to use and share your health information will expire when the research is completed.

Once your health information has been disclosed to a third party (for example, a pharmaceutical company participating in a study), federal privacy laws may no longer protect it from further disclosure.

You may change your mind and revoke (take back) this consent and authorization at any time and for any reason. To revoke this consent and authorization, you must contact the Principal Investigator, Rebecca Schnall, at 212-342-6886.

However, if you revoke your consent and authorization, you will not be allowed to continue taking part in the Research. Also, even if you revoke this consent and authorization, the Researchers and the Sponsor may continue to use and disclose the information they have already collected.

Identifiers, or pieces of information that might identify you, will be removed from the data that is collected and analyzed and, after such removal, the information could be used for future research studies without additional consent.

Compensation

All participants are eligible for up to $100: for completing surveys at baseline ($40), month 3 ($60).

Additional Costs

There are no costs to you for participating in this study, but you may incur data usage charges as a result of using the mLab App Plus.

Voluntary Participation

Your participation in the study is voluntary. You may decide not to participate in the study. If you decide to participate, you are free to withdraw from the study at any time. Your refusal to participate, or your early withdrawal, will not affect any benefits to which you are otherwise entitled nor will it affect the care provided by the members of your care team.

Additional Information

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.

If you have any questions or concerns about the study, you may contact: Dr. Rebecca Schnall at (212) 342-6886 or rb897@cumc.columbia.edu

If you have any questions about your rights as a research participant, or if you have a concern about this study, you may contact:

Human Research Protection Office Institutional Review Board

Columbia University Irving Medical Center

154 Haven Avenue, 2nd Floor

New York, NY 10032

Telephone: (212) 305-5883

Email: irboffice@columbia.edu

Columbia University IRB
IRB-AAAU3380 (Y03M00)
IRB Approval Date: 05/22/2024
For use until: 05/21/2025

An Institutional Review Board is a committee organized to protect the rights and welfare of human subjects involved in research.

More information about taking part in a research study can be found on the Columbia University IRB website at: http://www.cumc.columbia.edu/dept/irb.

Statement of Consent and HIPAA Authorization

I have read the consent form and HIPPA authorization, and talked about this research study, including the purpose, procedures, risks, benefits and alternatives with the researcher. Any questions I had were answered to my satisfaction. I am aware that by signing below, I am agreeing to take part in this research study and that I can stop being in the study at any time. I am not waiving (giving up) any of my legal rights by signing this consent form. I will be given a copy of this consent form to keep for my records.

Signatures

Participant Signature Lines

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2) Study Participant

Print Name _____

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3) Signature

_____

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4) Date

_____

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5) Person Obtaining Consent

Print Name _____

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6) Signature

_____

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7) Date

_____