mLab App for Improving Uptake of Rapid HIV Self-testing and Linking Youth to Care

Informed Consent Forms

NCT03803683

Dr. Rebecca Schnall

RM Consent Enroll Arm 1

Record ID _____

Columbia University Consent Form
Note: this document will be deployed, using REDCap, as an e-consent form

Protocol Information

Attached to Protocol: IRB-AAAR8760
Principal Investigator: Rebecca Schnall (rb897)
IRB Protocol Title: Mobile and Connected Health Interventions to Improve Care Continuum and Health Outcomes

General Information

Consent Number: CF-AABW2050
Participation Duration: 1 year
Anticipated Number of Subjects: 525 (New York: N=345, Chicago: N=180)
Research Purpose: The purpose of this study is to learn about HIV testing behavior and linkage to care among young adults. The secondary purpose of this study is to assess the performance of the mLab App for interpreting OraQuick test results.

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

Information on Research

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 that 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 HIV testing and linkage to care among young adults. If you agree to be in the study, the following will happen:

1. 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

2. As a participant in this study, you will complete a video-conference visit that will take about 2-3 hours with a member of the study team. As part of this visit you will complete an online survey and the following initial research procedures for the first visit:

3. During your first visit, you will receive the following:

a. mLab app - A mobile app on your phone that you will access using a login name and password. The app will provide HIV prevention information, push notification reminders for testing, step-by-step instructions for using the OraQuick HIV tests, an image upload function so you can send your results to the study team, and results from the OraQuick HIV tests. By using the app, we will ask you to test the app's ability to interpret the results of the OraQuick tests. If you test HIV positive, the mLab app will provide information on how to set up follow- up confirmatory testing within the following 24 hours. All information that you provide within the app will be stored on a secured server.

4. After your first visit, you will be sent the following:

a. 2 OraQuick HIV tests - These are HIV self-testing kits that you are encouraged to use at regular intervals (3 and 6 months from now) as part of research procedures. You will receive the OraQuick package insert with information about the tests. The OraQuick tests are for your individual use and should not be used for partner testing.

b. An email or text with links to mobile-optimized online prevention information, including PrEP and HIV testing information.

c. A study information card listing the study teams' contact information. The first study visit will take about 2-3 hours.

2. After the first visit, we will remind you to complete OraQuick HIV testing using the mLab app at 3 and 6 month intervals, and you will:

-be asked to manually enter the OraQuick test results; and
-be asked to take a picture of the test results for the app to analyze the results; and
-receive the app's interpretation of the OraQuick test results.

3. Six months after your initial appointment, you will receive 2 more OraQuick HIV tests and complete another survey. You will complete a similar follow up survey at 12 months after your initial appointment.

4. You may also receive text messages from the study team if you choose this method for communication. Text messages will not disclose study participation nor HIV status.

Technical Difficulties

If you have any technical difficulties using the mLab App or the OraQuick tests, please contact our study staff at:
Rafael Garibay
study phone: 347-743-0104

office phone:212-305-8198
e-mail: son-mlab@cumc.columbia.edu

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 you participation in any research associated with the current study. Please initial below to show whether or not you give permission for futurecontact.

(initial) I give permission to be contacted in the future for research purposes. _____

(initial) I give permission to be contacted in the future 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 OraQuick:
1. Subjects must follow package instructions on the OraQuick test and always read the test results from the OraQuick test themselves given that the accuracy of the mLab application has not been proven. Confirmatory HIV testing is still needed.

2. You may mistakenly believe that a negative result of the OraQuick Test means that you are not infected with HIV. There is a chance that the test does not detect an HIV infection. To offset this risk, you will be repeatedly told that a negative result in the OraQuick test does not mean that you are not HIV 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.

3. You may experience distress if you get a positive result in the OraQuick HIV 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.

4. There is a risk of receiving a false positive test result, meaning you have tested HIV positive, but are in fact HIV negative. You will be instructed on the limitations of the OraQuick Test, including that false positive results have occurred, which again stresses the need for confirmatory testing since results may change. Limitations of the OraQuick 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 testing also does not include testing for STIs. A positive result from the OraQuick 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 a HIV positive result while testing during this study, we will provide you with confirmatory testing referrals. A negative result in the OraQuick test generally means that HIV has not been detected in your body and that you are HIV uninfected. A negative result could also mean that you may have gotten HIV too recently for the test to detect it. Confirmatory HIV testing referrals will be made available to all subjects.

Risks Specific to the Use of the mLab App:
1. The mLab App is not FDA-approved for interpreting the OraQuick test. Results from the mLab app are investigational therefore your interpretation of the results from the OraQuick In-Home Test are the most appropriate to refer to.

2. There may be false positive results related to the performance of the mLab App, 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 imagine algorithm (e.g. lighting, geometries, and appropriately set processing thresholds) of the app.

Benefits Study participants may benefit from reflecting on sexual practices, discussing sexual-risk behavior, and by having an HIV test. If the results of the HIV test come back positive, you may benefit from having the chance to discuss the results with study staff, trained in pre- and post-test counseling. You will also be offered a confirmatory test referrals 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.

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 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.

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.

Vanderbilt University will have access to all data collected through the mLab App which includes but is not limited to the results of the OraQuick 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 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 Scharf, 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.

Compensation All participants are eligible for up to $170: for completing surveys at baseline ($40), month 6 ($55), and month 12 ($75).
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.

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.

If you choose to enroll in an HIV antibody study while enrolled in the mLab study, you will be withdrawn from the mLab study.

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 Medical Center
154 Haven Avenue, 1st Floor
New York, NY 10032
Telephone: (212) 305-5883
Email: irboffice@columbia.edu

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

I have read the e-consent form 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 electronically signing this e-consent form. I will be given a copy of this e-consent form to keep for my records.

Signatures
Participant Signature Lines

Study Participant
Print Name

_____

Signature

_____

Date

_____

RM Consent Enroll Arm 2

Record ID _____

Columbia University e-Consent Form
Note: this document will be deployed, using REDCap, as an e-consent form

Protocol Information

Attached to Protocol: IRB-AAAR8760
Principal Investigator: Rebecca Schnall (rb897)
IRB Protocol Title: Mobile and Connected Health Interventions to Improve Care Continuum and Health Outcomes

General Information

Consent Number: CF-AABW2000
Participation Duration: 1 year
Anticipated Number of Subjects: 525 (New York: N=345, Chicago: N=180)
Research Purpose: The purpose of this study is to learn about HIV testing behavior in 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

Detailed Information on Research Information on Research
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 that 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;
-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 HIV testing and linkage to care among young adults. If you agree to be in the study, the following will happen:
1. 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 during your first visit.

2. As a participant in this study, you will complete a video-conference call with a member of the study team to complete an online survey for the first visit, which will take about 1-2 hours. You will also receive a study information card listing the study teams' contact information.

3. 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.

4. Six months after your initial appointment, you will complete another survey. You will complete a similar follow up survey at 12 months after your initial appointment.

5. You may also receive text messages from the study team if you choose this method for communication. Text messages will not disclose study participation nor HIV status.

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.

Please initial below to show whether or not you give permission for future contact.

(initial) I give permission to be contacted in the future for research purposes. _____

(initial) I give permission to be contacted in the future for information relating to this study _____

Risks General risks
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.

Loss of confidentiality
A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of confidentiality or 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 'Confidentiality' section of this consent form.

Benefits Study participants may benefit from reflecting on sexual practices, discussing sexual-risk behavior.

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.

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 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.

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

The following individuals and/or agencies will be able to look at and copy your research records:
-The investigator, Columbia University 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')

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 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.

Compensation All participants are eligible for up to $170: for completing surveys at baseline ($40), month 6 ($55), and month 12 ($75).

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.

If you choose to enroll in an HIV antibody study while enrolled in the mLab study, you will be withdrawn from the mLab study.

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 Medical Center
154 Haven Avenue, 1st Floor
New York, NY 10032 Telephone: (212) 305-5883
Email: irboffice@columbia.edu

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
I have read the e-consent form 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 electronically 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 e-consent form. I will be given a copy of this e-consent form to keep for my records.

Signatures
Participant Signature Lines

Study Participant
Print Name

_____

Signature

_____

Date

_____

RM Consent Enroll Arm 3

Record ID _____

Columbia University Consent Form
Note: this document will be deployed, using REDCap, as an e-consent form

Protocol Information

Attached to Protocol: IRB-AAAR8760
Principal Investigator: Rebecca Schnall (rb897)
IRB Protocol Title: Mobile and Connected Health Interventions to Improve Care Continuum and Health Outcomes

General Information

Consent Number: CF-AABW1950
Participation Duration: 1 year
Anticipated Number of Subjects: 525 (New York: N=345, Chicago: N=180)
Research Purpose: The purpose of this study is to learn about HIV testing behavior in 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

Detailed Information on Research Information on Research

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;
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-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 HIV testing and linkage to care among young adults. If you agree to be in the study, the following will happen:
1. 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 during your first visit.

2. As a participant in this study, you will complete a video-conference call for 1-2 hours with a member of the study team. As part of this first visit, you will l to complete an online:
3. After your first visit, you will receive the following:

(a) 2 OraQuick HIV tests - These are HIV self-testing kits that you are encouraged to use at 3 and 6-month intervals as part of research procedures. You will receive the OraQuick package insert with information about the tests.
The OraQuick tests are for individual use and should not be used for

partner testing.

(b) Study information card listing the study teams' contact information.

4. 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.

5. Six months after your initial appointment, you will receive 2 more OraQuick HIV tests and complete another survey. You will complete a similar follow up survey at 12 months after your initial appointment.

6. You may also receive text messages from the study team if you choose this method for communication. Textmessages will not disclose study participation nor HIV status.

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Please initial below to show whether or not you give permission for future contact.

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Risks General risks
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.

Loss of confidentiality
A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of confidentiality or 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 'Confidentiality' section of this consent form.

Risks Specific to the Use of OraQuick:
1. Subjects must follow package instructions on the OraQuick test and always read the test results from the OraQuick test themselves. Confirmatory HIV testing is still needed.

2. You may mistakenly believe that a negative result of the Oraquick Test means that you are not infected with HIV. There is a chance that the test does not detect an HIV infection. To offset this risk, you will be repeatedly told that a negative result in the OraQuick test does not mean that you are not HIV 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.

3. You may experience distress if you get a positive result in the OraQuick HIV 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.

4. There is a risk of receiving a false positive test result, meaning you have tested HIV positive, but are in fact HIV negative. You will be instructed on the limitations of the OraQuick Test, including that false positive results have occurred, which again stresses the need for confirmatory testing since results may change. Limitations of the OraQuick 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 testing also does not include testing for STIs. A positive result from the OraQuick 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 a HIV positive result while testing during this study, we will provide you with confirmatory testing referrals. A negative result in the OraQuick test generally means that HIV has not been detected in your body and that you are HIV uninfected. A negative result could also mean that you may have gotten HIV too recently for the test to detect it. Confirmatory HIV testing referrals will be made available to all subjects.

Benefits Study participants may benefit from reflecting on sexual practices, discussing sexual-risk behavior, and by having an HIV test. If the results of the HIV test come back positive, you may benefit from having the chance to discuss the results with study staff, trained in pre- and post-test counseling.

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.

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 ensured. Despite all of our effort, 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 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.

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.

The following individuals and/or agencies will be able to look at and copy your research records:
-The investigator, Columbia University 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')

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.

Compensation All participants are eligible for up to $170: for completing surveys at baseline ($40), month 6 ($55), and month 12 ($75).

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.

If you choose to enroll in an HIV antibody study while enrolled in the mLab study, you will be withdrawn from the mLab study.

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 Medical Center
154 Haven Avenue, 1st Floor; New York, NY 10032
Telephone: (212) 305-5883 Email: irboffice@columbia.edu

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 I have read the e-consent form 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 electronically 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 e-consent form. I will be given a copy of this e-consent form to keep for my records.

Signatures
Participant Signature Lines

Study Participant
Print Name

_____

Signature

_____

Date

_____