Understanding HIV/STD Risk and Enhancing PrEP Implementation Messaging in a Diverse Community-Based Sample of Gay, Bisexual, and Other Men Who Have Sex with Men in a Transformational Era (MIC-DROP)

Attachment 5a. Consent to Participate English

Emory University
Consent to be a Research Subject

TITLE:	Understanding HIV/STD Risk and Enhancing PrEP Implementation Messaging in a Diverse Community-Based Sample of Gay, Bisexual, and Other Men Who Have Sex with Men in a Transformational Era (MIC-DROP Study)
PROTOCOL NO.:	None WCG IRB Protocol #20225896 STUDY00005355
SPONSOR:	Centers for Disease Control and Prevention
INVESTIGATOR:	Patrick Sullivan, DVM, PhD 1518 Clifton Rd NE CNR 2nd Floor - PRISM Atlanta, Georgia 30322 United States
STUDY-RELATED PHONE NUMBER(S):	404-712-8630 (24 hours)

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

You Are Being Asked to Be in a Research Study
Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study, you will be one of 1,275 people who are being studied at Emory University, San Diego State University, University of Chicago and Centers for Disease Control and Prevention (CDC).

Why is this study being done?
This study is being done to answer the question of how we can optimize the benefits of HIV pre-exposure prophylaxis (PrEP) for HIV-negative men who have sex with men (MSM). We will be asking participants to complete a series of online surveys that ask questions about their sexual health, including current HIV prevention strategies and preferences. Participants will also be asked to complete self-testing kits for HIV and other sexually transmitted infections (STIs). Some participants may be asked to

participate in additional optional elements of this study, such as focus-group discussions or in-depth interviews.

Do you have to be in the study?
It is your decision to be part of this research study. You do not have to be in it. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?
If you are eligible and want to be part of the study, you will participate for 2 years. The researchers will ask you to do the following: (1) attend a virtual enrollment visit and complete the baseline online survey to establish some basic facts about you for our study, such as your demographics, sexual history, medical history, behaviors, and attitudes; (2) complete seven online follow-up surveys with similar questions to the baseline survey; and (3) complete HIV and STI home testing kits every six months, starting today for a total of 4 tests throughout the study. There will be optional in-depth interviews and focus group discussions that you may be invited to participate in. You will be paid for most study procedures.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question. Additionally, you could benefit from at-home testing for HIV and STIs.

What are the risks or discomforts I should know about before deciding?
The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious, such as loss of privacy or breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study
If you choose not to participate in this study, there are still ways to obtain information on PrEP and access to HIV and STI testing from community providers and/or your physician.

Costs
There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

What Should I Do Next?
Read this form, or have it read to you. Take time to consider this and ask any questions you would like.

<u>Introduction</u>
You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any benefits.

Before making your decision:

- Please carefully read this form or have it read to you.

- Please ask questions to the study staff about anything that is not clear.

You can take a copy of this consent form to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form, you will not give up any legal rights.

What is the purpose of this study?

The purpose of this study is to learn about the preferences and behaviors towards HIV pre-exposure prophylaxis (PrEP) for HIV-negative men who have sex with men (MSM). PrEP is a medication people at risk for HIV take to prevent getting HIV from sex or injection drug use.

What will I be asked to do?

You will be asked to participate in a research study and to download the study app to your smartphone. We will ask you to complete a total of eight online surveys, including the baseline survey and seven additional follow-up surveys every 3-months. You will also be asked to complete at-home HIV and other STI testing every 6-months. We may also invite you to participate in optional focus-group discussions or in-depth interviews. The duration of the study is 24 months. You will be compensated for each of the surveys you complete.

Baseline Survey & App Download

If you choose to be in this study, we will ask you to attend a virtual enrollment visit and complete a baseline survey to establish some basic facts about you for our study, such as your demographics, sexual history, medical history, behaviors, and attitudes. This survey will take you approximately 1-hour to complete. Staff will then assist you in downloading and orient you to the study mobile app on your smart phone.

Quarterly Follow-Up Surveys

If you choose to be in this study, we will ask you to complete seven follow-up surveys at 3-month intervals, starting three months from today. These surveys will be like the survey you take today, with questions about your sexual history, medical history, behaviors, and attitudes. The surveys will take you approximately 1-hour to complete.

HIV and STI testing

Participants will be asked to complete HIV and STI home testing kits every six months (four rounds), starting today. At the end of the survey, you will be asked to provide your mailing address to receive these kits in unmarked, discrete packaging.

For the self-collected home testing every 6 months, you will receive printed instructions on self-administered finger prick blood draw methods. You will conduct 1-2 self-administered finger pricks, similar to the practice someone with diabetes might follow on a regular basis. Although this is a smaller needle than used for a traditional blood draw, you may experience more or less pain from it. The finger prick device is spring-loaded and encased in a plastic shell, so you will not see or manipulate the needle. Following the finger pricks, you will collect blood by collecting free flowing drops of blood from your finger on collection paper and by using a collection tube. This will be a small amount of blood, about 6 drops total. If the sight of blood makes you feel

light-headed, or if at any point you feel uncomfortable or wish to stop participating, please immediately notify study staff. You will also self-collect rectal, urine and throat samples. Collecting the specimens will take you at most one hour. The STI home testing kits screens for syphilis and oral, urethral, and rectal chlamydia and gonorrhea. After completing the self-collection, you will be asked to mail in the kits using the pre-paid and pre-labeled mailer. You will receive detailed printed instructions regarding how to self-collect each of these samples and how to ship them to the laboratory with the mailer.

If you would like to complete any of the home testing at one of our study locations, you will have the option of indicating that and a study team member will contact you to coordinate.

Once the study team has received your results from the testing facility, a study team member will contact you to deliver results and refer you to treatment services if you test positive for HIV or another STI.

If you have a positive test for HIV or an STI, state law requires us or the testing laboratory to report that positive test to the State Health Department for the purposes of statistics and service planning. Study staff will assist you in linking to care and treatment as soon as possible. Individuals testing HIV positive will not continue in the study once diagnosed. It is possible that the Health Department could contact you to offer referrals for care or help with getting your partners tested. These procedures are the same as if you were tested at a doctor's office or a clinic outside of this research study.

Who owns my study information and samples?

If you join this study, you will be donating your thoughts and opinions. You will not receive any token of appreciation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already gathered may be still be used for this study.

What are the possible risks and discomforts?

We believe this study poses minimal risk to you as a participant.

You may feel nervous, shy or uncomfortable while answering survey questions about sex acts and beliefs. However, you do not have to answer questions that you do not wish to answer. You may also stop participating and withdraw from the study at any time. There is the risk of a loss of confidentiality of your research-related information.

There is a possibility that someone may see the mobile app on your device. Because this app provides information about STIs and HIV, there is a risk of breach of privacy. To prevent this, we recommend closing out of the app and/or locking your mobile phone when you are not interacting with the app.

You may also find out you that you have HIV or other STIs. This may be upsetting to you. However, study staff will provide testing and treatment resources located in your community. It is possible that the study team will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to remain in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?
This study may directly benefit you because of the direct access to testing to HIV and STIs and links to resources about HIV and STIs. The study may also indirectly benefit you because we may learn about how to promote prevention services that can help reduce the health burden of HIV among men who have sex with men.

Will I be compensated for my time and effort?
You will get a token of appreciation for your time and effort for each completed study activity. You can receive a token up to $600 throughout the study depending on how many surveys you complete. Upon completing the baseline survey and HIV/STI testing, you will receive a $100 token of appreciation. You will receive a $100 token of appreciation for each quarterly follow up survey that includes HIV/STI testing, and a $50 token of appreciation for each quarterly survey that does not include the HIV/STI testing. All payments will be provided in the form of an electronic gift card that will be emailed to you.

You will be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, depending on the amount and method of payment. Some payment methods involve mail coming to your house, which may be seen by others in your household. You can decline payment if you are concerned about confidentiality, or you can talk to the study team to see if there are other payment options.

What are my other options?
If you decide not to enter this study, there are other options to access HIV testing, STI testing, and PrEP outside of this research study. The study staff will discuss the other options with you. You do not have to be in this study to receive HIV testing, STI testing or PrEP.

How will you protect my private information that you collect in this study?
Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Certificate of Confidentiality
This research project has a Certificate of Confidentiality from the Centers for Disease Control and Prevention (CDC). Unless you say it is okay, researchers cannot release information that may identify you for a legal action, a lawsuit, or as evidence. This protection applies to requests from federal, state, or local civil, criminal, administrative, legislative, or other proceedings. As an example, the Certificate would protect your information from a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT protect your information if a federal, state, or local law says it must be reported. For example, some laws require reporting of abuse, communicable diseases, and threats of harm to yourself or others. The Certificate CANNOT BE USED to stop a federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop reporting required by the U.S. Food and Drug Administration (FDA). The Certificate also DOES NOT stop your information from being used for other research if allowed by federal regulations.

Researchers may release your information when you say it is okay. For example, you may give them permission to release information to insurers, your doctors, or any other person not connected with the

research. The Certificate of Confidentiality does not stop you from releasing your own information. It also does not stop you from getting copies of your own information.

Storing and Sharing your Information

The data you provide will be stored securely, with all names and data that could be used to identify you removed. The data you provide are to be used only by study staff. Your contact details will be stored securely, for use only when contacting you for study activities described in this form. The data you provide will not be used for other research.

If you test positive for an STI and/or HIV, we will share your personally identifying information (PII) (e.g., name, date of birth, address, phone number) to refer you to treatment if you elect to have the study assist you.

We will not send you your individual results from this study with the exception of laboratory results that you will receive through the study app during the course of the study. All data that is entered into the app will be encrypted, which makes it unreadable unless a special password is used to make the information readable. The study team will not be able to see your mobile device activity outside of our app, they will only be able to see your completion of some activities in the study app through its admin web portal. You will be required to log in to the application with a username and password as an additional app security measure. When you finish the study, we will help you remove the app from your mobile device and you will no longer be able to log in to the app.

De-identified data from this study may be shared with the research community at large to advance science and health. Data from this study may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Costs

There will be no costs to you for being a part of this study, other than basic costs like travel. You will not be charged for any of the research activities.

Withdrawal from the Study

You have the right to leave a study at any time without penalty. The study team also has the right to remove you from this study without your consent for any reason and without necessarily explaining why. The study team may remove you from the study if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Confidentiality

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, the funder(s), the Emory Institutional Review Board, the Emory Office of Compliance, and WCG IRB. Study funders may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

People Who will Use/Disclose Your Information:
The following people and groups will use and disclose your information in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your information to conduct the study.
- Emory may use and disclose your information to run normal business operations.
- The Principal Investigator and research staff will share your information with other people and groups to help conduct the study or to provide oversight for the study.
- The following people and groups will use your information to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Other researchers and centers that are a part of this study.
    - Government agencies that regulate the research including: Office for Human Research Protections.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.

Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your information may be shared with that new institution and their oversight offices. Information will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent.

Contact Information
Contact study coordinator Rebecca Moges-Banks at 404-712-8630 or principal investigator Patrick Sullivan at 404-727-2038:

- if you have any questions about this study or your part in it,
- if you have questions, concerns or complaints about the research

Contact WCG IRB at 855-818-2289 or researchquestions@wcgirb.com:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.

Consent and Authorization

Consent for Future Contact for Optional Study/Studies:
Please indicate below if you consent to be contacted for future studies conducted by Emory University, San Diego State University, and University of Chicago. Only your contact information would be kept for this purpose. The data you provide today will not be used as a part of future Emory University, San Diego State University, and University of Chicago studies for which you may be contacted.

I would like my contact information stored for potential contact about participation in future Emory University, San Diego State University, and University of Chicago research studies.

( ) YES
( ) NO

Consent for MIC-DROP Study

Being in this study is entirely your choice. You have the right to refuse to participate or to stop taking the baseline survey at any time.

Please indicate if you agree to voluntarily participate in this study.

( ) Yes, I agree to participate in this study
( ) No, I do not agree to participate in this study

If Yes, send to landing page stating: STOP AND LET STAFF KNOW YOU CONSENTED

If No, send to landing page stating: THANK YOU FOR YOUR TIME!

San Diego State University
Consent to be a Research Subject

TITLE:	Understanding HIV/STD Risk and Enhancing PrEP Implementation Messaging in a Diverse Community-Based Sample of Gay, Bisexual, and Other Men Who Have Sex with Men in a Transformational Era (MIC-DROP Study)
PROTOCOL NO.:	None WCG IRB Protocol #20225896
SPONSOR:	Centers for Disease Control and Prevention
INVESTIGATOR:	Keith Horvath, PhD 6363 Alvarado Court Suite 250 San Diego, California 92120 United States
STUDY-RELATED PHONE NUMBER(S):	619-594-3346 404-712-8630 (24 hours)

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You Are Being Asked to Be in a Research Study
Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study, you will be one of 1,275 people who are being studied at Emory University, San Diego State University, University of Chicago and Centers for Disease Control and Prevention (CDC).

Why is this study being done?
This study is being done to answer the question of how we can optimize the benefits of HIV pre-exposure prophylaxis (PrEP) for HIV-negative men who have sex with men (MSM). We will be asking participants to complete a series of online surveys that ask questions about their sexual health, including current HIV prevention strategies and preferences. Participants will also be asked to complete self-testing kits for HIV and other sexually transmitted infections (STIs). Some participants may be asked to participate in additional optional elements of this study, such as focus-group discussions or in-depth interviews.

Do you have to be in the study?
It is your decision to be part of this research study. You do not have to be in it. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?
If you are eligible and want to be part of the study, you will participate for 2 years. The researchers will ask you to do the following: (1) attend a virtual enrollment visit and complete the baseline online survey to establish some basic facts about you for our study, such as your demographics, sexual history, medical history, behaviors, and attitudes; (2) complete seven online follow-up surveys with similar questions to the baseline survey; and (3) complete HIV and STI home testing kits every six months, starting today for a total of 4 tests throughout the study. There will be optional in-depth interviews and focus group discussions that you may be invited to participate in. You will be paid for most study procedures.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question. Additionally, you could benefit from at-home testing for HIV and STIs.

What are the risks or discomforts I should know about before deciding?
The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious, such as loss of privacy or breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study
If you choose not to participate in this study, there are still ways to obtain information on PrEP and access to HIV and STI testing from community providers and/or your physician.

Costs
There will be no costs to you for being a part of this study, other than basic costs like travel. You will not be charged for any of the research activities.

What Should I Do Next?
Read this form, or have it read to you. Take time to consider this and ask any questions you would like.

<u>Introduction</u>
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Before making your decision:
- Please carefully read this form or have it read to you.
- Please ask questions to the study staff about anything that is not clear.

You can take a copy of this consent form to keep, as well as a signed and dated copy of the Experimental Subject's Bill of Rights. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form, you will not give up any legal rights.

What is the purpose of this study?

The purpose of this study is to learn about the preferences and behaviors towards HIV pre-exposure prophylaxis (PrEP) for HIV-negative men who have sex with men (MSM). PrEP is a medication people at risk for HIV take to prevent getting HIV from sex or injection drug use.

What will I be asked to do?

You will be asked to participate in a research study and to download the study app to your smartphone. We will ask you to complete a total of eight online surveys, including the baseline survey and seven additional follow-up surveys every 3-months. You will also be asked to complete at-home HIV and other STI testing every 6-months. We may also invite you to participate in optional focus-group discussions or in-depth interviews. The duration of the study is 24 months. You will be compensated for each of the surveys you complete.

Baseline Survey & App Download

If you choose to be in this study, we will ask you to attend a virtual enrollment visit and complete a baseline survey to establish some basic facts about you for our study, such as your demographics, sexual history, medical history, behaviors, and attitudes. This survey will take you approximately 1-hour to complete. Staff will then assist you in downloading and orient you to the study mobile app on your smart phone.

Quarterly Follow-Up Surveys

If you choose to be in this study, we will ask you to complete seven follow-up surveys at 3-month intervals, starting three months from today. These surveys will be like the survey you take today, with questions about your sexual history, medical history, behaviors, and attitudes. The surveys will take you approximately 1-hour to complete.

HIV and STI testing

Participants will be asked to complete HIV and STI home testing kits every six months (four rounds), starting today. At the end of the survey, you will be asked to provide your mailing address to receive these kits in unmarked, discrete packaging.

For the self-collected home testing every 6 months, you will receive printed instructions on self-administered finger prick blood draw methods. You will conduct 1-2 self-administered finger pricks, similar to the practice someone with diabetes might follow on a regular basis. Although this is a smaller needle than used for a traditional blood draw, you may experience more or less pain from it. The finger prick device is spring-loaded and encased in a plastic shell, so you will not see or manipulate the needle. Following the finger pricks, you will collect blood by collecting free flowing drops of blood from your finger on collection paper and by using a collection tube. This will be a small amount of blood, about 6 drops total. If the sight of blood makes you feel light-headed, or if at any point you feel uncomfortable or wish to stop participating, please

immediately notify study staff. You will also self-collect rectal, urine and throat samples. Collecting the specimens will take you at most one hour. The STI home testing kits screens for syphilis and oral, urethral, and rectal chlamydia and gonorrhea. After completing the self-collection, you will be asked to mail in the kits using the pre-paid and pre-labeled mailer. You will receive detailed printed instructions regarding how to self-collect each of these samples and how to ship them to the laboratory with the mailer.

If you would like to complete any of the home testing at one of our study locations, you will have the option of indicating that and a study team member will contact you to coordinate.

Once the study team has received your results from the testing facility, a study team member will contact you to deliver results and refer you to treatment services if you test positive for HIV or another STI.

If you have a positive test for HIV or an STI, state law requires us or the testing laboratory to report that positive test to the State Health Department for the purposes of statistics and service planning. Study staff will assist you in linking to care and treatment as soon as possible. Individuals testing HIV positive will not continue in the study once diagnosed. It is possible that the Health Department could contact you to offer referrals for care or help with getting your partners tested. These procedures are the same as if you were tested at a doctor's office or a clinic outside of this research study.

Who owns my study information and samples?

If you join this study, you will be donating your thoughts and opinions. You will not receive any token of appreciation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already gathered may be still be used for this study.

What are the possible risks and discomforts?

We believe this study poses minimal risk to you as a participant.

You may feel nervous, shy or uncomfortable while answering survey questions about sex acts and beliefs. However, you do not have to answer questions that you do not wish to answer. You may also stop participating and withdraw from the study at any time. There is the risk of a loss of confidentiality of your research-related information.

There is a possibility that someone may see the mobile app on your device. Because this app provides information about STIs and HIV, there is a risk of breach of privacy. To prevent this, we recommend closing out of the app and/or locking your mobile phone when you are not interacting with the app.

You may also find out you that you have HIV or other STIs. This may be upsetting to you. However, study staff will provide testing and treatment resources located in your community. It is possible that the study team will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to remain in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?
This study may directly benefit you because of the direct access to testing to HIV and STIs and links to resources about HIV and STIs. The study may also indirectly benefit you because we may learn about how to promote prevention services that can help reduce the health burden of HIV among men who have sex with men.

Will I be compensated for my time and effort?
You will get a token of appreciation for your time and effort for each completed study activity. You can receive a token up to $600 throughout the study depending on how many surveys you complete. Upon completing the baseline survey and HIV/STI testing, you will receive a $100 token of appreciation. You will receive a $100 token of appreciation for each quarterly follow up survey that includes HIV/STI testing, and a $50 token of appreciation for each quarterly survey that does not include the HIV/STI testing. All payments will be provided in the form of an electronic gift card that will be emailed to you.

What are my other options?
If you decide not to enter this study, there are other options to access HIV testing, STI testing, and PrEP outside of this research study. The study staff will discuss the other options with you. You do not have to be in this study to receive HIV testing, STI testing or PrEP.

How will you protect my private information that you collect in this study?
Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Certificate of Confidentiality
This research project has a Certificate of Confidentiality from the Centers for Disease Control and Prevention (CDC). Unless you say it is okay, researchers cannot release information that may identify you for a legal action, a lawsuit, or as evidence. This protection applies to requests from federal, state, or local civil, criminal, administrative, legislative, or other proceedings. As an example, the Certificate would protect your information from a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT protect your information if a federal, state, or local law says it must be reported. For example, some laws require reporting of abuse, communicable diseases, and threats of harm to yourself or others. The Certificate CANNOT BE USED to stop a federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop reporting required by the U.S. Food and Drug Administration (FDA). The Certificate also DOES NOT stop your information from being used for other research if allowed by federal regulations.

Researchers may release your information when you say it is okay. For example, you may give them permission to release information to insurers, your doctors, or any other person not connected with the research. The Certificate of Confidentiality does not stop you from releasing your own information. It also does not stop you from getting copies of your own information.

Storing and Sharing your Information
The data you provide will be stored securely, with all names and data that could be used to identify you removed. The data you provide are to be used only by study staff. Your contact details will be stored

securely, for use only when contacting you for study activities described in this form. The data you provide will not be used for other research.

If you test positive for an STI and/or HIV, we will share your personally identifying information (PII) (e.g., name, date of birth, address, phone number) to refer you to treatment if you elect to have the study assist you.

We will not send you your individual results from this study with the exception of laboratory results that you will receive through the study app during the course of the study. All data that is entered into the app will be encrypted, which makes it unreadable unless a special password is used to make the information readable. The study team will not be able to see your mobile device activity outside of our app, they will only be able to see your completion of some activities in the study app through its admin web portal. You will be required to log in to the application with a username and password as an additional app security measure. When you finish the study, we will help you remove the app from your mobile device and you will no longer be able to log in to the app.

De-identified data from this study may be shared with the research community at large to advance science and health. Data from this study may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Costs

There will be no costs to you for being a part of this study, other than basic costs like travel. You will not be charged for any of the research activities.

Withdrawal from the Study

You have the right to leave a study at any time without penalty. The study team also has the right to remove you from this study without your consent for any reason and without necessarily explaining why. The study team may remove you from the study if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Contact Information

Contact principal investigator Keith Horvath at 619-594-3346 or 404-712-8630 (24 hours):

- if you have any questions about this study or your part in it,
- if you have questions, concerns or complaints about the research

Contact WCG IRB at 855-818-2289 or researchquestions@wcgirb.com:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.

Consent and Authorization

Consent for Future Contact for Optional Study/Studies:
Please indicate below if you consent to be contacted for future studies conducted by Emory University, San Diego State University, and University of Chicago. Only your contact information would be kept for this purpose. The data you provide today will not be used as a part of future Emory University, San Diego State University, and University of Chicago studies for which you may be contacted.

I would like my contact information stored for potential contact about participation in future Emory University, San Diego State University, and University of Chicago research studies.

( ) YES
( ) NO

Consent for MIC-DROP Study

Being in this study is entirely your choice. You have the right to refuse to participate or to stop taking the baseline survey at any time.

Please indicate if you agree to voluntarily participate in this study.

( ) Yes, I agree to participate in this study
( ) No, I do not agree to participate in this study

If Yes, send to landing page stating: STOP AND LET STAFF KNOW YOU CONSENTED

If No, send to landing page stating: THANK YOU FOR YOUR TIME!

The UNIVERSITY OF CHICAGO
The Division of the Biological Sciences • The University of Chicago Medical Center
Consent to be a Research Subject

TITLE:	Understanding HIV/STD Risk and Enhancing PrEP Implementation Messaging in a Diverse Community-Based Sample of Gay, Bisexual, and Other Men Who Have Sex with Men in a Transformational Era (MIC-DROP Study)
PROTOCOL NO.:	None WCG IRB Protocol #20225896
SPONSOR:	Centers for Disease Control and Prevention
INVESTIGATOR:	John Schneider, MD 5841 South Maryland Ave, MC5100 Chicago, IL 60637 USA
STUDY-RELATED PHONE NUMBER(S):	(773) 702-8349

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

You Are Being Asked to Be in a Research Study
Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study, you will be one of 1,275 people who are being studied at Emory University, San Diego State University, University of Chicago and Centers for Disease Control and Prevention (CDC).

Why is this study being done?
This study is being done to answer the question of how we can optimize the benefits of HIV pre-exposure prophylaxis (PrEP) for HIV-negative men who have sex with men (MSM). We will be asking participants to complete a series of online surveys that ask questions about their sexual health, including current HIV prevention strategies and preferences. Participants will also be asked to complete self-testing kits for HIV and other sexually transmitted infections (STIs). Some participants may be asked to participate in additional optional elements of this study, such as focus-group discussions or in-depth interviews.

Do you have to be in the study?
It is your decision to be part of this research study. You do not have to be in it. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?
If you are eligible and want to be part of the study, you will participate for 2 years. The researchers will ask you to do the following: (1) attend a virtual enrollment visit and complete the baseline online survey to establish some basic facts about you for our study, such as your demographics, sexual history, medical history, behaviors, and attitudes; (2) complete seven online follow-up surveys with similar questions to the baseline survey; and (3) complete HIV and STI home testing kits every six months, starting today for a total of 4 tests throughout the study. There will be optional in-depth interviews and focus group discussions that you may be invited to participate in. You will be paid for most study procedures.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question. Additionally, you could benefit from at-home testing for HIV and STIs.

What are the risks or discomforts I should know about before deciding?
The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious, such as loss of privacy or breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study
If you choose not to participate in this study, there are still ways to obtain information on PrEP and access to HIV and STI testing from community providers and/or your physician.

Costs
There will be no costs to you for being a part of this study, other than basic costs like travel. You will not be charged for any of the research activities.

What Should I Do Next?
Read this form, or have it read to you. Take time to consider this and ask any questions you would like.

<u>Introduction</u>
You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any benefits.

Before making your decision:
- Please carefully read this form or have it read to you.
- Please ask questions to the study staff about anything that is not clear.

You can take a copy of this consent form to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form, you will not give up any legal rights.

What is the purpose of this study?

The purpose of this study is to learn about the preferences and behaviors towards HIV pre-exposure prophylaxis (PrEP) for HIV-negative men who have sex with men (MSM). PrEP is a medication people at risk for HIV take to prevent getting HIV from sex or injection drug use.

What will I be asked to do?

You will be asked to participate in a research study and to download the study app to your smartphone. We will ask you to complete a total of eight online surveys, including the baseline survey and seven additional follow-up surveys every 3-months. You will also be asked to complete at-home HIV and other STI testing every 6-months. We may also invite you to participate in optional focus-group discussions or in-depth interviews. The duration of the study is 24 months. You will be compensated for each of the surveys you complete.

Baseline Survey & App Download

If you choose to be in this study, we will ask you to attend a virtual enrollment visit and complete a baseline survey to establish some basic facts about you for our study, such as your demographics, sexual history, medical history, behaviors, and attitudes. This survey will take you approximately 1-hour to complete. Staff will then assist you in downloading and orient you to the study mobile app on your smart phone.

Quarterly Follow-Up Surveys

If you choose to be in this study, we will ask you to complete seven follow-up surveys at 3-month intervals, starting three months from today. These surveys will be like the survey you take today, with questions about your sexual history, medical history, behaviors, and attitudes. The surveys will take you approximately 1-hour to complete.

HIV and STI testing

Participants will be asked to complete HIV and STI home testing kits every six months (four rounds), starting today. At the end of the survey, you will be asked to provide your mailing address to receive these kits in unmarked, discrete packaging.

For the self-collected home testing every 6 months, you will receive printed instructions on self-administered finger prick blood draw methods. You will conduct 1-2 self-administered finger pricks, similar to the practice someone with diabetes might follow on a regular basis. Although this is a smaller needle than used for a traditional blood draw, you may experience more or less pain from it. The finger prick device is spring-loaded and encased in a plastic shell, so you will not see or manipulate the needle. Following the finger pricks, you will collect blood by collecting free flowing drops of blood from your finger on collection paper and by using a collection tube. This will be a small amount of blood, about 6 drops total. If the sight of blood makes you feel light-headed, or if at any point you feel uncomfortable or wish to stop participating, please immediately notify study staff. You will also self-collect rectal, urine and throat samples.

Collecting the specimens will take you at most one hour. The STI home testing kits screens for syphilis and oral, urethral, and rectal chlamydia and gonorrhea. After completing the self-collection, you will be asked to mail in the kits using the pre-paid and pre-labeled mailer. You will receive detailed printed instructions regarding how to self-collect each of these samples and how to ship them to the laboratory with the mailer.

If you would like to complete any of the home testing at one of our study locations, you will have the option of indicating that and a study team member will contact you to coordinate.

Once the study team has received your results from the testing facility, a study team member will contact you to deliver results and refer you to treatment services if you test positive for HIV or another STI.

If you have a positive test for HIV or an STI, state law requires us or the testing laboratory to report that positive test to the State Health Department for the purposes of statistics and service planning. Positive test results will be reported to the Illinois Department of Public Health. The information provided will be your name, date of birth, age, sex, race/ethnicity, address, telephone number and date of HIV test. The database that keeps track of this information is labeled with a unique identification number so that your name does not appear with your HIV status. This helps keep your name private.

Study staff will assist you in linking to care and treatment as soon as possible. Individuals testing HIV positive will not continue in the study once diagnosed. It is possible that the Health Department could contact you to offer referrals for care or help with getting your partners tested. These procedures are the same as if you were tested at a doctor's office or a clinic outside of this research study.

Who owns my study information and samples?

If you join this study, you will be donating your thoughts and opinions. You will not receive any token of appreciation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already gathered may be still be used for this study.

What are the possible risks and discomforts?

We believe this study poses minimal risk to you as a participant.

You may feel nervous, shy or uncomfortable while answering survey questions about sex acts and beliefs. However, you do not have to answer questions that you do not wish to answer. You may also stop participating and withdraw from the study at any time. There is the risk of a loss of confidentiality of your research-related information.

There is a possibility that someone may see the mobile app on your device. Because this app provides information about STIs and HIV, there is a risk of breach of privacy. To prevent this, we recommend closing out of the app and/or locking your mobile phone when you are not interacting with the app.

You may also find out you that you have HIV or other STIs. This may be upsetting to you. However, study staff will provide testing and treatment resources located in your community. It is possible that the

study team will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to remain in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

This study may directly benefit you because of the direct access to testing to HIV and STIs and links to resources about HIV and STIs. The study may also indirectly benefit you because we may learn about how to promote prevention services that can help reduce the health burden of HIV among men who have sex with men.

Will I be compensated for my time and effort?

You will get a token of appreciation for your time and effort for each completed study activity. You can receive a token up to $600 throughout the study depending on how many surveys you complete. Upon completing the baseline survey and HIV/STI testing, you will receive a $100 token of appreciation. You will receive a $100 token of appreciation for each quarterly follow up survey that includes HIV/STI testing, and a $50 token of appreciation for each quarterly survey that does not include the HIV/STI testing. All payments will be provided in the form of an electronic gift card that will be emailed to you.

What are my other options?

If you decide not to enter this study, there are other options to access HIV testing, STI testing, and PrEP outside of this research study. The study staff will discuss the other options with you. You do not have to be in this study to receive HIV testing, STI testing or PrEP.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Certificate of Confidentiality

This research project has a Certificate of Confidentiality from the Centers for Disease Control and Prevention (CDC). Unless you say it is okay, researchers cannot release information that may identify you for a legal action, a lawsuit, or as evidence. This protection applies to requests from federal, state, or local civil, criminal, administrative, legislative, or other proceedings. As an example, the Certificate would protect your information from a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT protect your information if a federal, state, or local law says it must be reported. For example, some laws require reporting of abuse, communicable diseases, and threats of harm to yourself or others. The Certificate CANNOT BE USED to stop a federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop reporting required by the U.S. Food and Drug Administration (FDA). The Certificate also DOES NOT stop your information from being used for other research if allowed by federal regulations.

Researchers may release your information when you say it is okay. For example, you may give them permission to release information to insurers, your doctors, or any other person not connected with the research. The Certificate of Confidentiality does not stop you from releasing your own information. It also does not stop you from getting copies of your own information.

Storing and Sharing your Information

The data you provide will be stored securely, with all names and data that could be used to identify you removed. The data you provide are to be used only by study staff. Your contact details will be stored securely, for use only when contacting you for study activities described in this form. The data you provide will not be used for other research.

If you test positive for an STI and/or HIV, we will share your personally identifying information (PII) (e.g., name, date of birth, address, phone number) to refer you to treatment if you elect to have the study assist you.

We will not send you your individual results from this study with the exception of laboratory results that you will receive through the study app during the course of the study. All data that is entered into the app will be encrypted, which makes it unreadable unless a special password is used to make the information readable. The study team will not be able to see your mobile device activity outside of our app, they will only be able to see your completion of some activities in the study app through its admin web portal. You will be required to log in to the application with a username and password as an additional app security measure. When you finish the study, we will help you remove the app from your mobile device and you will no longer be able to log in to the app.

De-identified data from this study may be shared with the research community at large to advance science and health. Data from this study may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Costs

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Contact Information

Contact study coordinator Bella Matthews at (773)702-8349 or principal investigator Dr. John Schneider at (773) 702-8349

- if you have any questions about this study or your part in it,
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