

**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 5c. In-Depth Interview Consent English

Emory University
Oral Consent and Script/Information Sheet
For a Research Study – Interview Sub-study Addendum

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)

This form has more information about the research study. It may add to or change the information in the consent form you signed at the start of this study. You will receive a copy of this consent form addendum for your records.

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.

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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.

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Before making your decision:

- Please carefully read this information sheet or have it read to you
- Please listen to the study staff explain the study to you
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Who owns my study information and samples?

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What are the possible risks and discomforts?

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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 read a new information sheet and provide new verbal consent if you decide to stay in the study.

Will I benefit directly from the study?

This interview portion of the study is not designed to benefit you directly. Doing this research study may not benefit you personally. We may learn about how to promote prevention services that can help reduce the health burden of HIV among MSM.

Will I be compensated for my time and effort?

You will receive \$75 for each interview you take part in as a token of appreciation to you for your time and effort, for a total of \$225 for all three interviews. 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.

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 information sheet. The data you provide will not be used for other research.

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.

Withdrawal from the Study

You have the right to leave a study at any time without penalty. The study team also have the right to remove you from in this study without your consent for any reason. 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 IBR. 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:
 - o 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.
 - o Other researchers and centers that are a part of this study.
 - o Government agencies that regulate the research including: Office for Human Research Protections.
 - o Public health agencies.
 - o Research monitors and reviewer.
 - o 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

If you have questions about this study, your part in it, your rights as a research participant, or if you have questions, concerns or complaints about the research you may contact the following:

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

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- o You have questions, concerns, or complaints that are not being answered by the research team.
- o You are not getting answers from the research team.
- o You cannot reach the research team.
- o You want to talk to someone else about the research.
- o You have questions about your rights as a research subject.

Do you have any questions about anything in the informational sheet? Were there any parts that seemed unclear?

Do you agree to take part in the study?

[Participant agrees to participate (circle one): Yes No]

[If Yes:]

Signature of Person Conducting Informed Consent Discussion

Date Time

Name of Person Conducting Informed Consent Discussion

San Diego State University
Oral Consent and Script/Information Sheet
For a Research Study – Interview Sub-study Addendum

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)

This form has more information about the research study. It may add to or change the information in the consent form you signed at the start of this study. You will receive a copy of this consent form addendum, as well as a signed and dated copy of the Experimental Subject's Bill of Rights for your records.

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[Participant agrees to participate (circle one): Yes No]

[If Yes:]

Signature of Person Conducting Informed Consent Discussion

Date Time

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The UNIVERSITY OF CHICAGO
The Division of the Biological Sciences • The University of Chicago Medical Center
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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

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Do you have any questions about anything in the informational sheet? Were there any parts that seemed unclear?

Do you agree to take part in the study?

[Participant agrees to participate (circle one): Yes No]

[If Yes:]

_____	_____	_____
Signature of Person Conducting Informed Consent Discussion	Date	Time

Name of Person Conducting Informed Consent Discussion