Development and Testing of an HIV Prevention Intervention Targeting Black Bisexually-Active Men

Attachment 4

Consent Forms by Site

4a PHMC:
Consent Form for Study Participation

Flesch-Kincaid = 7.9
ID # _____

Connections Project Participant Consent Form

A. Study Purpose

You are being asked to take part in a study for men who have sex with both men and women.

- The Connections project's purpose is to learn about the lives of Black men who have sex with men and women. It will also help us develop programs and services for them.
- We are testing a new program to help men protect themselves and their partners against HIV and improve their overall health. We are inviting 250 men in Philadelphia to join this study.
- The Public Health Management Corp. (PHMC) is carrying out the project. It is being funded by the Centers for Disease Control and Prevention (CDC). The COLOURS Organization is also a part of this project.

B**. Study Activities**

If you agree to be in the study, you agree to these activities:

1. **Take a two-part computer-assisted interview** about your health, lifestyle, drug use, sexual behaviors and feelings about HIV *(about 45 minutes)*. In the first part, you will read and listen to some questions on the computer and record your answers on the computer. In the second part, an interviewer will ask you some questions and record your answers on a computer. You can refuse to answer any question at any time.

2. **Provide us with contact information** *(about 10 minutes)*. We will ask for your addresses, phone numbers, and family and friends who know how to locate you. We will use this information to schedule follow-up interviews and send reminders about appointments. It is important for the Connections program to have all the men come back for their follow-up interviews. We want to find out how you are doing and how the program is working. All of your contact information will be kept in a secured location separate from all of your interview information.

3. **Be assigned to attend one of two individual sexual health programs: life-coaching or health counselor.** You will be randomly selected into a program, which means that the program you attend is selected by chance. In both programs, you will be offered the chance to get HIV and STI testing.

    i. If you are assigned to the life-coaching program, you will meet with your life coach for six private sessions *(about 90 to 120 minutes each session for a total of 9 to 12 hours)*. The sessions will occur on a weekly basis over the next 6 to 8 weeks. You can choose a time for your sessions that is good for you. The sessions will allow you to

explore your life, relationships, behaviors and attitudes. Your life coach will help you make plans to improve your health and deal with life problems. You will also discuss how to reduce your risk for getting and giving HIV.

ii. If you are assigned to the health counselor program, you will meet with a counselor for one private session *(about 1 hour)*. The counselor will discuss ways to reduce your HIV risk and improve your health.

4. **You may be asked to help recruit other Black men who have sex with both men and women to take part in this program.** Your interviewer will tell you more about how to recruit these men *(about 10 minutes*). If you do not want to help recruit other men for Connections, you can still take part in the study.

5. **You will come back for 2 more computer-assisted interviews.** Both of these interviews will be like the one you take today. The next interview will take place about 2 months from now and take about 25 minutes. The third and final interview will take place about 5 months from now, and take about 45 minutes. We are interested in knowing how you are doing after attending the Connections program. We also want to find out how we can improve the program.

C. <u>Confidentiality</u>

The information you share in the 3 interviews, as well as what you talk about in your sessions will be kept private as much as allowed by law. Your name, address and other locating information will be kept separate from the answers you give during the interviews. You will have a chance to tell us what type of message we should leave in case we need to contact you.

If you decide to test for HIV or other sexually transmitted infections (STI), your test results will not be shared with the Connections' research staff.

All program files will be kept locked. To protect your privacy, we will keep the records under a code number rather than by name. The answers you give us will be stored on a password-protected computer to which only research staff will have access. Your name, address or other facts that might identify you will not appear when we present the study results. In no way will your answers be linked back to you. The answers you give us will be combined with answers from other participants.

D. <u>Voluntary Participation</u>

Agreeing to be a part of the Connections program is up to you. You are free to join the project or not. If you do not join, you will not lose any health care service that you expect to get apart from this study. We can provide referral sources if you need to talk with someone, but don't want to join the study. If you decide to join the study, you are also free to drop out at any time for any reason. In that case, too, you will not lose any health care service that you may expect apart from this study.

E. <u>Risks</u>

You may have these risks or problems from being in the study:

1. You may experience distress when answering questions about certain areas of your life. Your interviewer can provide referrals for services, if needed.

2. You may experience disappointment because you were not assigned to the program you wanted. Someone on the staff can help refer you to other programs for men in the community.

3. If you participate in this study, people may find out that you have sex with men and women. To lessen this risk, staff members have been trained to keep all that you say private, including your name. Instead of your name, a code number will be placed on your interview. This consent form and any contact information (e.g., phone number, address) you give us will be stored apart from your interviews.

4. If you agree to take a syphilis test and/or need to take a second confirmatory HIV test, you may experience slight discomfort or pain from the blood draw. You may also experience anxiety while you wait for your test results. You will not receive your HIV/STI test results from the Connections program. You will need to go back to the location where you took your HIV/STI tests to receive your results.

F. Benefits

The personal benefits you will get from being in the study may include:

1. You will have the opportunity to discuss important issues and experiences that have impacted your life. You will learn effective strategies to cope with stressors or obstacles.

2. You will learn about ways to improve your health and reduce the risk for HIV and other STIs for you and your partners.

3. You will learn about health care and other services, incase you need them.

4. You will have the opportunity to learn your HIV and STI status. Common STIs are chlamydia, gonorrhea, and syphilis. If you find out you have HIV or other STIs, you will receive referrals for medical care and other services you may need.

5. By sharing your thoughts and experiences, you can help others. You will help us to develop better programs and services for men in the community.

G. Costs

There is no cost to you for taking part in this study.

H. Reimbursement

To thank you for your time and to offset any costs to you, we will reimburse you for each completed interview (total of 3 interviews) and to recruit other participants.

1. You will receive a total of $50 in two payments for the 1st computer-assisted interview. You will receive the first payment of $25 immediately after finishing today's interview and the second payment of $25 when you return for your first session.

2. For each session you attend, you will receive a raffle ticket for a drawing to win a prize. The prize will be worth $100 and drawings will be held every two months.

3. You may be asked to recruit 3 to 5 of your friends. For each man you recruit, who joins the Connections program, you will receive $15.

4. For your 2nd computer-assisted interview that will occur around 2 months from now, you will receive $50 right after completing it.

5. For your 3rd and final interview that will occur around 5 months from now, you will receive $75 right after completing it.

J. <u>Ending Your Participation</u>

We will not allow you to be a part of the study if you are visibly drunk, stoned, sleepy, unable to focus or behave in an improper manner. If we do not allow you to be a part of the study for any of these reasons, you will only be given money to cover transportation costs. You can decide to stop participating in the study at any time.

K. Agreement

I agree to take part in the 3 project interviews. I also agree to be randomly selected to attend one of two sexual health programs. I have been told all the terms and conditions of the study. Any questions I had have been answered. I may leave now or stop the interview after it starts. If I have questions about the project, I may call Lee Carson, Project Coordinator, at 267-765-2352. I may also call Mr. Carson if I feel taking part in this study has harmed me. My choice to take part in this study or to refuse to answer any question will not affect my present or future status as a client or employee at PHMC or COLOURS Organization. I will get a copy of this consent form.

If I have any questions about the project, I may contact the director of this project, Dr. Jennifer Lauby. Her mail address is PHMC, 260 S. Broad St. 18th floor, Philadelphia, PA 19102. Her phone number is 215 985-2556 and email is Jennifer@phmc.org. If I have questions about my rights as part of this project, I may call Dr. Lynne Kotranski. She is the contact person for the PHMC Institutional Review Board. Her phone number is 215 985-2552.

_____ _____

Signature of Participant Date

_____ _____

Signature of Staff obtaining consent Date

CONNECTIONS PROJECT (PHMC)
CONSENT FORM FOR AUDIO RECORDING LIFE COACH SESSION

You have agreed to join the Connections Project. We are now asking for your permission to audiotape one of your sessions with your life coach. The purpose for the recording is to help us find out if the program is meeting your needs and achieving its goals. If you agree, this will be the only session we will record during your involvement with the Connections Project.

The audio recording and the information you give us will be kept private. That means they will be shared only with Connections' staff. Your name will never appear on the recording. Your name, address and other contact information will be kept in a locked file separate from the recording. The recording will be erased two weeks from today.

Having your session recorded is voluntary. That means you can still take part in the Connections Project, but we will not record the session if you don't want us to. Having your session recorded or not will not change how the Connections' staff treats you.

You will get a copy of this form to take with you.

I agree to have my session _#____ audio recorded as part of the Connections Project. Information about this project has been explained to me. I understand that the answers I give in the session are private and that having the session recorded is voluntary.

_____ _____
Signature of Participant Date

_____ _____
Signature of Counselor Date

4b Nova:
Consent Form for Study Participation

John H. Stroger, Jr. Hospital of Cook County
1901 West Harrison Street, Chicago, Illinois 60612
312.864.6000 • TDD 312.864.0100

Cook County Bureau of Health Services

Todd H. Stroger
President
Board of Cook County Commissioners

Robert R. Simon, M.D.
Interim Chief
Bureau of Health Services

Johnny C. Brown
Chief Operating Officer

INFORMED CONSENT for Participation in

***POWER:* Bisexual African-American Men's Study Intervention Trial**
Flesch-Kincaid Grade Level – 8.3

Principal Investigator: Sybil Hosek, PhD

Address: Department of Psychiatry
Administration Building
1900 W. Polk Street, 8th Floor
Chicago, IL 60612

Telephone: (312) 864-8030

INTRODUCTION

The purpose of this consent form is to give you the information you will need to help decide whether or not to be in this study. We want you to ask any questions you may have about the study. When all of your questions have been answered, you can decide if you want to be in the study. This process is called "informed consent." Once we answer your questions and if you still want to take part in the study, you will be asked to sign this consent form. You will then be given a copy of the form to keep.

DO I HAVE TO JOIN THIS STUDY?

Your participation in this research study is completely voluntary. You decide whether or not you want to be in this research study. Refusing to join the study

will not change your usual healthcare or involve any loss of benefits for you. If you decide to join the study, you may stop being in it at any time.

WHAT IS THIS STUDY ABOUT?

This research study is funded by the Centers for Disease Control and Prevention (CDC). About 240 Black men 18 years or older will be part of this study. The purpose of this study is to test the HIV risk reduction program. The program is delivered on the Internet. It is for Black men who have sex with both women and men. We want to know if this program can help men make healthy choices to reduce their risk of getting HIV. The program is a series of one-on-one sessions that look at situations that put Black men at risk for HIV and other infections.

HOW LONG WILL THE STUDY LAST?

This research study will last about 4 years. However, your participation in this study will last about four months.

WHAT WILL I HAVE TO DO IN THE STUDY?

If you agree to join the study, we will ask you to set a date to come to our study office at TaskForce. At that visit, you will complete a 60-90 minute survey on a computer. The survey will be delivered to you using a computer-generated interview format called ACASI (Audio Computer-Assisted Self-Interview). An ACASI uses a computer and voice recordings so you can hear (through headphones) and see (on the screen) each question and the answer choices for that question. You will enter your answer right into the computer. When the interview is complete, the computer "locks in" your information so no one can see how you answered.

The survey will ask you to give information about your background, living situation, drug and alcohol use, sexual behaviors, incarceration history, and other health behaviors. Some of these questions are very personal, but everything is confidential. You do not have to answer any question that you don't want to answer. You can end the interview at any time if you do not want to continue. Once you are done answering the questions, the information will then be put into a secret code (encrypted) that we cannot read. It is then sent to a central location.

After you finish the survey, you will then be randomly assigned to receive one of two programs. Random assignment means that neither you nor the research team have a choice about which program you receive. Both programs focus on healthy living. As a part of both programs, we will offer you a referral for free HIV and STI testing. You can accept or decline the referral.

In total, we will ask you to commit to three weekly sessions on the Internet. You can access the Internet from your home or another place where you have Internet access. If you don't have Internet access, you may use the computers at TaskForce. These sessions will take about 60 minutes each and will be scheduled at times convenient for you. If you sign-on to an Internet session late, we may ask to reschedule your scheduled session for a future date. We will provide specific instructions to help you log into the session. After the last session, we will ask you to complete an online survey about your opinion of the sessions.

After you finish all three Internet sessions, we will ask you to come back to the TaskForce office within a week to take a second survey. Finally, we will ask you to complete one last survey about three months after you completed the second one. It will take about 60 to 90 minutes to complete the survey each time. Because we will contact you to confirm dates and times, we will ask for your contact information (such as name and telephone number) so the research staff can get in touch with you.

WHAT ARE SOME POSSIBLE RISKS?

Taking part in this study does not involve any physical risk to you. However, there is some risk that answering some of the questions may be uncomfortable or upsetting. You do not have to answer any question that you do not want to answer. At any point, you may stop if you do not wish to continue the survey.

You will be talking about topics related to sex, drugs, and HIV. These topics may make you feel embarrassed or awkward. If you become upset, we will give information about services available at local agencies. The study will not pay for these services.

All information collected in this study will be secure. By secure we mean that only the members of the study team will be able to review the information you tell us, however there is always the potential for loss of confidentiality. We cannot promise that the risks we told you about or other unknown problems will not happen.

WHAT ARE THE BENEFITS TO ME?

You may gain information, skills, and insight that could help you lead a healthier life. You will have the chance to learn about risks associated with HIV and ways to reduce your risk of getting HIV. If you do not know your HIV status, you will have the chance to receive a referral for HIV testing.

WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS STUDY (WHAT OTHER CHOICES DO I HAVE)?

You may choose not to join this study or stop participating at anytime. Whether you decide to be in this study or not, it will not change your ability to be in other studies in the future. Also, it will not change your ability to receive health care services from John H. Stroger Hospital of Cook County.

ARE THERE ANY COSTS TO ME FOR TAKING PART IN THIS STUDY?

Taking part in the study will not cost you anything.

WHAT WILL I GET FOR TAKING PART IN THIS STUDY?

To thank you for your time, we will give you $25 in gift cards per Internet session. You will also get $40 cash for completing the first survey; $50 for completing the second survey; and $60 for the third survey. We will also give you $15 for each person that you refer to the POWER study that actually enrolls into it.

WHAT IF NEW FINDINGS DEVELOP DURING THE COURSE OF THE STUDY?

Any new findings that may develop during the course of the study and may affect your willingness to be in this study will be brought to your attention by the research staff.

ARE THERE ANY REASONS WHY I MAY BE ASKED TO STOP TAKING PART IN THE STUDY?

Although you may choose to stop taking part in this study at any time, the following are other reasons you may have to stop taking part in the study:

- The person in charge of the study decides that being in the study would be harmful to you;
- If you seem to become very upset or angry when completing the surveys, you may be asked to end your part in the study, and you will be given the chance to speak with a counselor;
- If you are not able to do what the study needs you to do (for example, the study staff cannot reach you for two or three months);
- You are incarcerated or placed in detention;
- The study is canceled by the Centers for Disease Control and Prevention

WILL MY TAKING PART IN THE STUDY BE KEPT PRIVATE?

All information collected in this study will be maintained in a secure manner. To protect your privacy, we will assign a unique number to you which will be kept in a locked cabinet in the Project Director's office. We will protect all study materials by keeping them in a locked file cabinet or in a password protected computer. Your contact information will also be kept in a locked cabinet in a locked room at the research site. It will only be accessible to research staff that

need to contact you for study participation follow-up. Only study staff will have access.

Every effort will be made to keep your participation and your personal information secure, but absolute confidentiality cannot be guaranteed. For example, if we learn something that would immediately put you or others in danger, the researchers are required by law to take steps to keep you and others safe. This means that we may have to report to the authorities (hospital, police, or social services) any information you tell us that suggests that you might be in danger, such as if you tell us that you plan to harm yourself or harm others, or if you tell us that someone is abusing or neglecting you. We will also report if you tell us that you are abusing someone under the age of 18.

The only people that may see your personal information are:

- Cook County Bureau of Health Services Institutional Review Board (IRB)
- Study staff
- Study monitors
- Ethics committees

These people will review your records under guidelines of the U.S. Federal Privacy Act. Their job is to make sure that the study is doing what it is supposed to and that research participants are protected. If your study records are reviewed, your identity could become known to them.

To assure that the appropriate steps are being taken to protect the rights and welfare of humans' participants as subjects in research, the Cook County Bureau of Health Services, John H. Stroger Hospital of Cook County (Institutional Review Board), FDA, and other Regulatory Agencies may monitor and review the research study at different times as required by law.

WHAT HAPPENS IF I AM INJURED?

If you are injured as a result of being in this research study, you will then be told where you could receive treatment for your injuries. No money or other forms of compensation will be provided by the hospital or sponsoring agency for such injuries.

WHO DO I CONTACT IF I HAVE PROBLEMS OR QUESTIONS ABOUT THE STUDY?

The researcher in charge of this study at John H. Stroger Hospital of Cook County is Sybil Hosek, PhD. The project director is Alicia Ozier. Both of them can be called at (312) 864-8030 or (312) 864-8009 if you have any questions about this

study before or after you take part in the study or if you become injured as a result of taking part in this study.

Also, if you have any questions about your rights as a research participant, you may call the Institutional Review Board at Cook County Bureau of Health Services (IRB) and ask to speak with IRB Quality Assurance Officer at (312) 864-4821 during regular business hours.

STATEMENT OF CONSENT

The details of this study were explained to you, and you were given the chance to ask any questions you wished. The person performing this research study told you that your participation in this study is voluntary. You may be a participant in it only if you wish, and you may refuse to participate or may stop participating at any time without in any way impacting your future treatment at this hospital.

By signing this consent document, you are agreeing to take part in the study described to you. You will be given a copy of this consent form to keep.

Participant's Name (print)	Participant's Signature	Date

PI or Designee's statement:

I have reviewed this study and the consent form with the participant. To the best of my knowledge, he understands the purpose, procedures, risks, and benefits of the study.

PI or Designee's Name (print)	PI or Designee's Signature	Date

NOTE: This consent form with the original signatures MUST be retained on file by the principal investigator. A copy must be given to the participant.

4c CSU:
Consent Form for Study Participation

Informed Consent Form (without COC)
(Flesch-Kincaid reading level: 8.3)

California State University, Dominguez Hills
Consent to Act as a Research Subject

Health Intervention Study

You are being asked to take part in a study. A staff member will read this form to you. If you do not know the meaning of a word, or group of words, please ask the staff member. A staff member will also answer any other questions.

Investigators of this study are:

- **Ricky N. Bluthenthal, Ph.D., Urban Community Research Center and Sociology Department, California State University Dominguez Hills (CSUDH), 310-243-3500.**
- **Nina Harawa, Ph.D., MPH, Charles Drew University (CDU), 310-563-5899.**

You are being asked to take part in this study because you are an African American man who has just been in jail or prison and reported that you have had sex with both men and women in the last 12 months. We are going to sign up about 260 men to take part in this study.

The Purpose of this Study is to see if a new group activity can help African American men protect themselves from HIV and sexually transmitted infections (STIs). This study is funded by the Centers for Disease Control and Prevention.

Study Activities: If you agree to be a part of this study, you will be asked to do the following:

1) Tell us how to contact you. We will ask about how to contact you through family, friends, and public records. The things you tell us will be kept private. That is, we will not tell anyone what you said and we will not tell anyone that you were part of this study.

2) Complete three surveys about your health history, sexual likes and dislikes, what you or your partner do when you have sex, people who support you, alcohol and drug use, mental health, HIV issues, and use of testing services. You will complete one survey now. This will take about 60 minutes to finish. You will be asked to complete a second survey in about 6 weeks. This second survey should take about 45 minutes to complete. The last survey will be given to you 4 months from now and should take about 60 minutes.

3) When you come back for your second interview you will be offered testing for STIs. It is your choice if you want to be tested or not.

4) You may be asked to tell other people about the study. This is your choice.

5) You will be chosen at random (like a coin flip) to join 1 of 2 different groups. You will have a 50/50 chance of being in either group. The groups are as follows:

- Group 1 will join the Men in Life Environments (MILE) program. As part of this program you will be asked to join in 6 group meetings over the next 4 to 6 weeks. The goal of this program is to help you make healthy life choices. Each of the meetings will be tape-recorded so that we can be sure that staff is giving the program to you correctly. You will also receive services from the Center for Health Justice. These services can help you with getting a job, a place to stay, and link you to other services after jail or prison

- Group 2 will only receive services from the Center for Health Justice.

Risks and Discomforts: You will be asked questions about your personal activities and history. Answering these questions may cause stress or discomfort. You do not have to answer questions that cause you stress or discomfort. In addition, study staff will talk to you about what you thought about the survey and will put you in touch with people who can give you social and medical services if needed. You may be asked to take part in group meetings. This could also cause stress or discomfort. You do not have to answer questions during these group meetings. You may leave any group talk if you choose. You may speak with the person in charge of the group or one of the Investigators privately (i.e., Drs. Bluthenthal or Harawa) about any concerns that you have. If you need additional counseling, you can get a referral to low-cost counseling by calling the Department of Mental Health Services ACCESS Center at 1-800-854-7771.

You may be on parole or probation. This may prevent you from having contact with felons, gang members, or being in school and church zones but these rules do not apply to being a part of this study because it is a program that assists people who have just left jail.

Study Benefits: By being a part of this study, you may learn things that can make your health better and help you make better choices. You may also have higher cultural and racial pride and more people to support you by meeting people similar to you. You will also be offered free STI testing.

This study also benefits society through what is learned from you about the social and health needs of people like you. What is learned from the study may be used to help make new programs that could assist African American men.

Confidentiality: The things you tell us will be kept private as possible. We will not tell anyone what you said and we will not tell anyone that you were part of this study. The surveys will not ask you to give your name. Reports from this study will not include your name or anything else that can be linked back to you. What you tell us in the three surveys will not be stored with your name. A number will be linked to your name. What you tell us, your contact information, and the name-ID link will be stored in a secure manner and only study staff will have access to it.

We ask that everything shared during the group meetings be kept private but we cannot be sure that what you say during the groups will stay private. In group meetings, you should share only as much as you feel okay with sharing. The people leading the groups will not ask you personal questions. Instead, they will ask all group members to share their stories so more bonding and social relationships can happen.

In certain cases, we may have to tell someone that you are a part of this study. If you report the sexual or physical abuse of a child or elderly adult or if you threaten violence to self or others, we will report these events or work through other outside support staff to make sure that these events are reported. In addition, if you ask us in writing, we will give out details about your activities in this study.

Voluntary Nature of Participation: You do not have to be in this study, it is up to you if you want to or not. Your choice will not change your relationship with any service giver, California State University Dominguez Hills (CSUDH), or Charles Drew University (CDU). You may choose to not answer any question. If you choose to be a part of the study, you are free to withdraw your consent and stop at any time without affecting your future care at CSUDH, CDU, and the Martin Luther **King**, Jr. Multi-Service Ambulatory Care **Center.**

If you are a CSUDH or a CDU student, you may choose not to be a part of this study or to stop being a part of the study at any time. This will not affect your grades or class standing at CSUDH or CDU. You will not be offered or given any special treatment if you are a part of this study.

If you are a CSUDH or CDU employee, you being a part of this study is in no way part of your college duties, and if you choose not to be a part of the study your employment with these colleges, or the benefits related to your employment will not be affected. You will not be offered or get any special treatment if you are a part of this study.

Being a part of this study will in no way affect the terms of your parole or probation. Nor will it affect any future legal cases.

Withdrawal of participation by the investigator: The Investigators may stop you from being a part of the study at anytime if they think it is best. If you feel a lot of stress that makes you want to stop, you may have to drop out even if you would like to continue. If you disrupt the group regularly (for example, name calling or threatening others) or are high or drunk, you may have to drop out even if you would like to continue. If you are asked to leave the group, this decision is made to protect your health and safety or because you are not a good fit for the study. If you are asked to leave, you will still be paid at a later point for being a part of that group.

Reimbursement and Incentives: You may receive between $120 and $240 cash total based on which group you are put into and how many tasks you finish.

If you are in the treatment group, you will be paid $30 for completing the first survey, $20 for each treatment group, $20 for the second survey and $40 for the third survey ($210 total). People that refer other eligible persons to the study may get up to $30. After the first session, you will be able to miss no more than two group talks. If a group talk is missed, you are required to complete a make-up session with one of the staff group leaders before taking part in the next group talk. If you miss two or more sessions without making them up, you will not be allowed to continue in the remaining group talks. You will be able to complete remaining interviews and receive reimbursement.

If you are in the compared group, a total of $120 is may be given to you ($30 for the first survey, $20 for the second survey, $40 for third survey, and up to $30 for referring up to 3 people to the study).

Who to call: If you have any questions or concerns about this study you may call the Principal Investigator, Ricky Bluthenthal at 310-243-3500. If you have questions about your rights as a research participant, you may call the Institutional Review Board for the Protection of Human Subjects at CSUDH at 310-243-3756.

We will provide you with a copy of this consent form for your records.

SIGNATURE OF RESEARCH SUBJECT

I have read (or someone has read to me) and understand the information provided above. I have been given a chance to ask questions, all of my questions have been answered and I am satisfied. I have been given a copy of this form, as well as a copy of the Subject's Bill of Rights.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO BE A PART OF THE STUDY IT DESCRIBES.

_____
Name of Subject

_____ _____
Signature of Subject Date

Consent to allow tape-recording

Parts of the study will involve you being tape-recorded. The main reason for the tape recording is to evaluate the people carrying out the program. Your name or other things that identify you will not be included in the written records that are made from the recordings. When they are not being used, the tape recordings will be kept in a locked file cabinet in the secured office of Dr. Bluthenthal or Dr. Harawa. We will not report any thing about any single person and all reports will talk about the group as a whole.

Please check the box below that applies to you and put your initials in the space:

_____ I agree to be tape-recorded.

_____ I do not want to be tape-recorded.

SIGNATURE OF INVESTIGATOR or REPRESENTATIVE

I have explained the research to the subject and answered all of his questions. I believe that he understands the information described in this document and freely consents to participate.

_____ _____

Name of Investigator/Representative Date

Informed Consent Form (with COC)
(Flesch-Kincaid reading level: 8.3)

California State University, Dominguez Hills
Consent to Act as a Research Subject

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You are being asked to take part in a study. A staff member will read this form to you. If you do not know the meaning of a word, or group of words, please ask the staff member. A staff member will also answer any other questions.

Investigators of this study are:

- **Ricky N. Bluthenthal, Ph.D., Urban Community Research Center and Sociology Department, California State University Dominguez Hills (CSUDH), 310-243-3500.**
- **Nina Harawa, Ph.D., MPH, Charles Drew University (CDU), 310-563-5899.**

You are being asked to take part in this study because you are an African American man who has just been in jail or prison and reported that you have had sex with both men and women in the last 12 months. We are going to sign up about 260 men to take part in this study.

The Purpose of this Study is to see if a new group activity can help African American men protect themselves from HIV and sexually transmitted infections (STIs). This study is funded by the Centers for Disease Control and Prevention.

Study Activities: If you agree to be a part of this study, you will be asked to do the following:

1) Tell us how to contact you. We will ask about how to contact you through family, friends, and public records. The things you tell us will be kept private. That is, we will not tell anyone what you said and we will not tell anyone that you were part of this study.

2) Complete three surveys about your health history, sexual likes and dislikes, what you or your partner do when you have sex, people who support you, alcohol and drug use, mental health, HIV issues, and use of testing services. You will complete one survey now. This will take about 60 minutes to finish. You will be asked to complete a second survey in about 6 weeks. This second survey should take about 45 minutes to complete. The last survey will be given to you 4 months from now and should take about 60 minutes.

3) When you come back for your second interview you will be offered testing for STIs. It is your choice if you want to be tested or not.

4) You may be asked to tell other people about the study. This is your choice.

5) You will be chosen at random (like a coin flip) to join 1 of 2 different groups. You will have a 50/50 chance of being in either group. The groups are as follows:

- Group 1 will join the Men in Life Environments (MILE) program. As part of this program you will be asked to join in 6 group meetings over the next 4 to 6 weeks. The goal of this program is to help you make healthy life choices. Each of the meetings will be tape-recorded so that we can be sure that staff is giving the program to you correctly. You will also receive services from the Center for Health Justice. These services can help you with getting a job, a place to stay, and link you to other services after jail or prison

- Group 2 will only receive services from the Center for Health Justice.

Risks and Discomforts: You will be asked questions about your personal activities and history. Answering these questions may cause stress or discomfort. You do not have to answer questions that cause you stress or discomfort. In addition, study staff will talk to you about what you thought about the survey and will put you in touch with people who can give you social and medical services if needed. You may be asked to take part in group meetings. This could also cause stress or discomfort. You do not have to answer questions during these group meetings. You may leave any group talk if you choose. You may speak with the person in charge of the group or one of the Investigators privately (i.e., Drs. Bluthenthal or Harawa) about any concerns that you have. If you need additional counseling, you can get a referral to low-cost counseling by calling the Department of Mental Health Services ACCESS Center at 1-800-854-7771.

You may be on parole or probation. This may prevent you from having contact with felons, gang members, or being in school and church zones but these rules do not apply to being a part of this study because it is a program that assists people who have just left jail.

Study Benefits: By being a part of this study, you may learn things that can make your health better and help you make better choices. You may also have higher cultural and racial pride and more people to support you by meeting people similar to you. You will also be offered free STI testing.

This study also benefits society through what is learned from you about the social and health needs of people like you. What is learned from the study may be used to help make new programs that could assist African American men.

Confidentiality: The things you tell us will be kept private as possible. We will not tell anyone what you said and we will not tell anyone that you were part of this study. The surveys will not ask you to give your name. Reports from this study will not include your name or anything else that can be linked back to you. What you tell us in the three surveys will not be stored with your name. A number will be linked to your name. What you tell us, your contact information, and the name-ID link will be stored in a secure manner and only study staff will have access to it.

We ask that everything shared during the group meetings be kept private but we cannot be sure that what you say during the groups will stay private. In group meetings, you should share only as much as you feel okay with sharing. The people leading the

groups will not ask you personal questions. Instead, they will ask all group members to share their stories so more bonding and social relationships can happen.

To help keep information about you confidential, we have also obtained a Confidentiality Certificate from the Centers for Disease Control and Prevention (CDC). The Confidentiality Certificate adds special protection for research information that identifies you. The Confidentiality Certificate will protect the investigators from being forced, even under a court order or subpoena, to release information that could identify you. However, in a few circumstances, we may be required to disclose your participation in this study. If you report the sexual or physical abuse of a child or elderly adult or if you threaten violence to self or others, we will report these incidents or work through supportive agencies to ensure that these incidents are reported. In addition, if you ask us in writing, we will give out details about your activities in this study.

Voluntary Nature of Participation: You do not have to be in this study, it is up to you if you want to or not. Your choice will not change your relationship with any service giver, California State University Dominguez Hills (CSUDH), or Charles Drew University (CDU). You may choose to not answer any question. If you choose to be a part of the study, you are free to withdraw your consent and stop at any time without affecting your future care at CSUDH, CDU, and the Martin Luther **King**, Jr. Multi-Service Ambulatory Care **Center.**

If you are a CSUDH or a CDU student, you may choose not to be a part of this study or to stop being a part of the study at any time. This will not affect your grades or class standing at CSUDH or CDU. You will not be offered or given any special treatment if you are a part of this study.

If you are a CSUDH or CDU employee, you being a part of this study is in no way part of your college duties, and if you choose not to be a part of the study your employment with these colleges, or the benefits related to your employment will not be affected. You will not be offered or get any special treatment if you are a part of this study.

Being a part of this study will in no way affect the terms of your parole or probation. Nor will it affect any future legal cases.

Withdrawal of participation by the investigator: The Investigators may stop you from being a part of the study at anytime if they think it is best. If you feel a lot of stress that makes you want to stop, you may have to drop out even if you would like to continue. If you disrupt the group regularly (for example, name calling or threatening others) or are high or drunk, you may have to drop out even if you would like to continue. If you are asked to leave the group, this decision is made to protect your health and safety or because you are not a good fit for the study. If you are asked to leave, you will still be paid at a later point for being a part of that group.

Reimbursement and Incentives: You may receive between $120 and $240 cash total based on which group you are put into and how many tasks you finish.

If you are in the treatment group, you will be paid $30 for completing the first survey, $20 for each treatment group, $20 for the second survey and $40 for the third survey ($210 total). People that refer other eligible persons to the study may get up to $30. After the first session, you will be able to miss no more than two group talks. If a group talk is missed, you are required to complete a make-up session with one of the staff group leaders before taking part in the next group talk. If you miss two or more sessions without making them up, you will not be allowed to continue in the remaining group talks. You will be able to complete remaining interviews and receive reimbursement.

If you are in the compared group, a total of $120 is may be given to you ($30 for the first survey, $20 for the second survey, $40 for third survey, and up to $30 for referring up to 3 people to the study).

Who to call: If you have any questions or concerns about this study you may call the Principal Investigator, Ricky Bluthenthal at 310-243-3500. If you have questions about your rights as a research participant, you may call the Institutional Review Board for the Protection of Human Subjects at CSUDH at 310-243-3756.

We will provide you with a copy of this consent form for your records.

SIGNATURE OF RESEARCH SUBJECT

I have read (or someone has read to me) and understand the information provided above. I have been given a chance to ask questions, all of my questions have been answered and I am satisfied. I have been given a copy of this form, as well as a copy of the Subject's Bill of Rights.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO BE A PART OF THE STUDY IT DESCRIBES.

_____
Name of Subject

_____ _____
Signature of Subject Date

Consent to allow tape-recording

Parts of the study will involve you being tape-recorded. The main reason for the tape recording is to evaluate the people carrying out the program. Your name or other things that identify you will not be included in the written records that are made from the recordings. When they are not being used, the tape recordings will be kept in a locked file cabinet in the secured office of Dr. Bluthenthal or Dr.

Harawa. We will not report any thing about any single person and all reports will talk about the group as a whole.

Please check the box below that applies to you and put your initials in the space:

_____ I agree to be tape-recorded.

_____ I do not want to be tape-recorded.

SIGNATURE OF INVESTIGATOR or REPRESENTATIVE

I have explained the research to the subject and answered all of his questions. I believe that he understands the information described in this document and freely consents to participate.

_____ _____
Name of Investigator/Representative Date

Informed Consent Form for STI Screening
(Flesch-Kincaid reading level: 9.2)

California State University, Dominguez Hills
Consent to Screen for Gonorrhea and Chlamydia

Today, we are offering testing for gonorrhea and Chlamydia infection. A staff member will read this form to you. If you do not understand or know the meaning of a word or sentence, please ask a staff member. A staff member will also answer any other questions.

Investigators of the MILE study are:

- **Ricky N. Bluthenthal, Ph.D., Urban Community Research Center and Sociology Department, California State University Dominguez Hills (CSUDH), 310-243-3500.**
- **Nina Harawa, MPH, Ph.D., Charles Drew University (CDU), 310-563-5899.**

You are being offered testing for gonorrhea and Chlamydia infection because you are a part of the HJ MILE study. All HJ MILE study members will be offered this testing. This testing is your choice.

Description:
If you agree to be tested for gonorrhea and Chlamydia, you will be asked to finish the following steps:

- Get counseling and urine-based testing for gonorrhea and Chlamydia infection. The counseling will explain the meaning of the test results and how to avoid sexually transmitted infections.
- You will be asked to return within two weeks to find out the results of these tests.

Risks and Discomforts:
The tests call for giving a urine sample. No pain or health risks are involved. Private bathrooms are on hand for the collection of samples. No other testing, such as drug testing, will be done on the sample. You may feel some stress as you wait for your test results. If you need additional counseling, you can get a referral to low-cost counseling by calling the Department of Mental Health Services ACCESS Center at 1-800-854-7771.

Benefits to You and Society:
You will get free testing for gonorrhea and Chlamydia infection. This testing will identify any gonorrhea or Chlamydia infections that you may be carrying inside of your body. Identifying these infections will allow you to have them treated and cured. Free treatment for these infections is offered in a number of places in Los Angeles. The treatment is simple and works well.

If you are found to have an infection, you will be informed on how and where to obtain treatment, or you may choose to obtain treatment through your regular doctor.

Treatment will allow you to avoid the harmful long-term effects of these infections and passing them on to your sexual partners.

Although most men notice signs of gonorrhea, about 10 % of men do not. When untreated, this infection can cause pain, stop you from being able to get a woman pregnant, and problems that are more serious.

About half of all men with Chlamydia do not notice any problems. Complications of Chlamydia among men are rare. However, the infection sometimes spreads to the tube that carries sperm from the testis, causing pain, fever, and, rarely, stops you from being able to get a woman pregnant.

Both Chlamydia and gonorrhea can stop a woman from being able to get pregnant and more serious problems in women if untreated.

Alternatives to participation:
If you choose not to be tested through this study, you may get free testing at one of the county's public health centers. These places may not offer test-related counseling. However, they may also have testing for other STDs, such as syphilis or may be able to test for gonorrhea and Chlamydia in the throat or rectum. Four places are listed below:

CENTRAL HEALTH CENTER

241 N. Figueroa St., Los Angeles, CA 90012

(213) 240-8203

JWCH INSTITUTE, CENTER FOR COMMUNITY HEALTH

522 South San Pedro Street

Los Angeles, CA 90013

(213) 622-2639

HOLLYWOOD SUNSET FREE CLINIC

3324 Sunset Blvd., Los Angeles, CA 90026

323) 660-5715, (323) 660-2400

SOUTH HEALTH CENTER

1522 E. 102nd St., Los Angeles, CA 90002
(323) 563-4112

Confidentiality:
Your test results will be kept private based on what the law allows. Study details, how you can be contacted, and the name-ID link will be stored in a secure manner and only study staff will have access to it. According to state laws, if you test positive for either gonorrhea or Chlamydia infection, we will report your name to the Los Angeles County Department of Public Health. They will keep these details private.

Voluntary Nature of Participation:

It is your choice to accept testing or not. Your choice to test or not test will not affect your relationship with the study or with any service givers, California State University Dominguez Hills (CSUDH), or Charles Drew University (CDU). If you decide to be a part of this study, you are free to withdraw your consent and stop at any time without affecting your future care at CSUDH, CDU, and or the Martin Luther King, Jr. Multi-Service Ambulatory Care Center.

If you are a CSUDH or a CDU student, you may choose not to be a part of this study or to stop being a part of the study at any time. This will not affect your grades or class standing at CSUDH or CDU. You will not be offered or given any special treatment if you are a part of this study.

If you are a CSUDH or CDU employee, your participation in this research is in no way part of your university duties, and if you choose not to be a part of the study your employment with these universities, or the benefits related to your employment will not be affected. You will not be offered or get any special treatment if you are a part of this study.

Reimbursement and Incentives:
You will not be paid or charged for taking these tests.

Whom to Contact:
If you have any questions or concerns about this study, you may call the investigator, Ricky Bluthenthal at 310-243-3500. If you have questions about your rights as a research participant, you may call the Institutional Review Board for the Protection of Human Subjects at CSUDH at 310-243-3756.

We will provide you with a copy of this consent form for your records.

SIGNATURE OF RESEARCH SUBJECT

I have read (or someone has read to me) and understand the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form, as well as a copy of the Subject's Bill of Rights.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO ACCEPT TESTING FOR GONORRHEA AND CHLAMYDIA.

_____
Name of Subject

_____ _____
Signature of Subject Date

SIGNATURE OF INVESTIGATOR or REPRESENTATIVE

I have explained the research to the subject and answered all of his questions. I believe that he understands the information described in this document and freely consents to participate.

_____ _____

Name of Investigator/Representative Date

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