

## **Attachment 13**

### **INFORMED CONSENT**

#### *Critical Thinking and Cultural Affirmation (CTCA) HIV Prevention Intervention for African American Men who have Sex with Men (AAMSM)*

Principal Investigator: Darrell P. Wheeler, Ph.D., M.P.H.  
Phone Number: 312.915.7005

#### **A. Purpose**

You are being asked to take part in a study of a program to help stop the spread of HIV (the virus that causes AIDS). Loyola University Chicago, Black Men's Xchange, and the Centers for Disease Control and Prevention (CDC) are conducting this research. Taking part in this study is up to you. The information below will help you make an informed choice about whether or not to take part. We hope to learn if a six-session group program can help African American men who have sex with men make important decisions to avoid getting or giving HIV. We are asking you to take part in this study because you are an African American man who has sex with men (MSM) and you are between the ages of 18 and 55. By taking part in this study, you may be in groups with other African American MSM. We expect about 430 men to take part in this study.

#### **B. What Will Happen:**

If you choose to take part (consent), the following will happen:

1. Today's visit will last approximately 2 hours. At today's visit you will fill out a survey. The survey asks questions about your health, sex life, cultural identity, and emotions. You will fill out the survey on a computer so no one will see your answers when you are on the computer. A staff member will show you how to fill out the survey and will be nearby to help if you have problems. You will also be asked to give us information about how to find you so that we can remind you of your next visit. Finally, you will be randomly assigned to one of two groups.

##### **a. Group Assignment**

1. If you are assigned to the intervention group, you will take part in a weekend-long group retreat. You will participate in a group that discusses African American history and culture, identity, and HIV risk behaviors among African American men who have sex with men. The first day would take about three hours on a Friday night, about 8 hours on Saturday, and about 9 hours on Sunday (This includes times for socializing and meals). You would not be staying overnight at the retreat facility. You will schedule a weekend to complete the program. Project staff may observe program sessions.

2. If you are assigned to the control group, you will not be participating in the retreat.
3. No matter which group you are in, you will receive electronic messages twice per month about basic men's health and wellness which will provide you with the chance to participate in a raffle for cash or prizes by responding to the message.
2. We will ask you to return to our study site for two more visits, one in 3 months, and one in 6 months. At these visits, we will ask you to fill out a questionnaire on the computer asking the same kinds of questions that were on the questionnaire you will fill out today, at your first visit.
3. At the end of the visit in 6 months, we will also ask you to fill out a brief exit survey. You may also be invited to complete an exit interview with a trained staff member to talk about your experience with the study.
4. If you move away from this city during the study, we will make other arrangements for your follow-up visit. We will conduct the follow-up visit over the phone from here.

### **C. Privacy**

Your research records will be kept private to the extent permitted by law. We cannot promise complete privacy. To protect your privacy, we will give you a study ID number. Your name will not be on the survey data or any recorded materials (including exit interview recordings). Personal information from your records will be locked at our study site and will not be talked about by our staff in the groups. Your personal information will not be given to anyone without your written approval, including the CDC. We will send your survey answers to the CDC, but we will only give them your study ID number. We will not give them your name.

If you are assigned to the group that participates in the retreat, you will be interacting with other men in group sessions. We ask that everyone in the group sessions not share private information about each other outside of the group, but we cannot guarantee it.

We will ask you for your name and address so we can remind you about your visits and send you information about men's health and wellness. Your name and address will be kept in a separate locked file from the survey forms and test results. The information from this study may be published in scientific journals or presented at scientific meetings but your identity will be kept secure.

We will keep your name and other contact information in a computer file and in a locked drawer at the Principal Investigator's (Dr. Darrell Wheeler) office that can only be opened by the study staff. Only study staff with a need for this information will have access to it.

**D. Exceptions to Privacy**

Abuse of a child by a parent or someone legally responsible for a child must be reported to child welfare services. If you are 18 years or older and report physical abuse of or sexual contact with a child for whom you are legally responsible, then staff will report your name to the child welfare services.

**E. Risks and Discomforts**

Possible risks and discomforts you could experience during this study include:

1. If you are assigned to the group that attends the retreat, you may share your own experiences with others in the group. Being in group meetings involves a loss of privacy. We cannot promise that other group members will keep your information to themselves (private). To minimize any loss of privacy, the group leaders will ask the group to keep all information talked about during the program to themselves. Also, the group will be asked to use first names or your name of choice only.
2. If you are assigned to the group that attends the retreat, the topics of discussion may cause you to become emotional. One purpose of the group is to help you express and cope with uncomfortable emotions. You may choose not to participate in any discussions which make you feel too uncomfortable and may withdraw from the study at any time. Also, there may be questions on the survey that make you feel uncomfortable or are hard to answer. You may leave any question blank and you can stop taking the survey and/or withdraw from the study at any time. The study staff will try to answer any questions you have and discuss any concerns you may have about the survey.

**F. Benefits**

The potential benefits of your taking part in this study include:

1. If you take part in the groups, you may gain insight about yourself and your identity.
2. You will get education on preventing HIV and sexually transmitted diseases.
3. If you do not already know your HIV status, you will get information about where to get a free HIV test.

**G. Costs**

There will be no costs to you as a result of taking part in this research study other than your time.

**H. Tokens of appreciation**

You will be given tokens of appreciation for time and travel. You will receive the following after completing each visit:

- \$25 gift card and a two-way CTA Transit Pass for the first visit (baseline appointment),

- 3 two-way CTA Transit Pass (1 for each day of the retreat), only if you are in the group that participates in the retreat
- \$25 gift card and a two-way CTA Transit Pass for the 3-month follow-up visit,
- \$50 gift card and a two-way CTA Transit Pass for the 6-month follow-up visit, and
- \$50 gift card and a two-way CTA Transit Pass for the exit interview (if you are selected).

If you are in the group that attends the retreat, you will also receive food during the retreat. Additionally, regardless of the group you are in, when you respond to the twice monthly electronic messages, you will be automatically entered to win one of 3 raffle prizes after completing the 3-month follow-up visit. The grand prize is will be prize valued at approximately \$140 such as a Kindle e-reader. the second prize \$50 gift card, and the third prize is a \$25 gift card.

The maximum amount of reimbursement a participant could receive for successfully completing the study is \$289 in gift cards and an e-reader.

#### **I. Termination from this Study without your Consent**

You may be removed from the study and told about other resources if:

- (a) the research team decides that the program would not be helpful to you, or
- (b) if you disrupt the group sessions

If the person who runs the study decides to remove you from the study, you will not come to any more sessions, nor will you receive reimbursement for any more sessions.

#### **J. Voluntary Participation and Withdrawal Statement**

Your taking part in this research study is up to you. Your choice of whether or not to take part will not interfere with your right to health care or other services to which you are otherwise entitled. You are not giving up any legal claims or rights because you are taking part in this study. If you do decide to take part, you are free to take back your consent and stop taking part at any time. If you stop, there is no penalty or loss of services to which you are otherwise entitled.

#### **L. Injury Statement**

Although not likely, in the event you are harmed while taking part in this study and need medical treatment, we will refer you to get care. We may refer you to a nearby hospital for emergency care (if needed) or give you a referral for other medical care. However, Loyola University Chicago, Black Men's Xchange, and the Centers for Disease Control and Prevention do not pay for this treatment. Signing this form does not mean that you are giving up any legal rights to be paid for harm that results from being in this study. For more information about this, you may contact the Principal Investigator listed in this form.

**M. Offer to Answer Questions**

If you ever have questions or problems about this study or in case of study-related injuries, you should contact:

Darrell Wheeler, Ph.D., M.P.H. at 312.915.7005

**If you have questions about your rights as a research participant, you may contact the Loyola University Office of Research Services at (773) 508-2689**

You may also write the IRB office:

Dr. Andrew Ellis  
Loyola University Chicago  
820 N. Michigan Avenue  
Chicago, IL 60611

You will be given a copy of this form to keep.

**N. Agreement**

I have read (or someone has read to me) the information provided above. I have been given the chance to ask questions and all of my questions have been answered to my satisfaction. I am free not to join this study, or to stop being in this study at any point. I know that project staff may observe the program and counseling sessions and if I am selected to participate in the exit interview this interview will be audio recorded. My signature below indicates that I have chosen to take part in this research.

Please sign your name and check the boxes below if:

- ☐ you have read this consent form (or had it explained to you),
- ☐ all your questions have been answered and
- ☐ you agree to take part in this study.

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Name of Study Volunteer	Signature of Study Volunteer	Date
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Name of Investigator/Person Obtaining Informed Consent	Signature	Date
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***This consent form is only valid if it carries the IRB approval stamp with current dates.***