3.3 Qualitative Interview Informed Consent

Form Approved OMB NO. _____ Exp. Date _____

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Flesch-Kincaid Grade Level 6.7

A. Study Purpose

You are being asked to take part in a research study. The study is being done by [name of Institution] and the Centers for Disease Control and Preventions (CDC). The study looks at relationships between men and women and how those relationships may place women at risk for getting HIV. HIV is the virus that causes AIDS.

It is up to you if you want be part of the study. To help you decide if you want to join the study we will tell you about:

- **1.** why the study is being done
- 2. what will happen if you join the study
- 3. what the possible risks of the study are
- 4. what the possible benefits of the study are
- 5. your rights as a person in the study

In this study, we will hold 20 individual interviews in [site]. We hope to interview a total of 60 women at our three study sites. We are inviting Black and Latina women who did a computer interview for our main study to be in this study too.

We hope the conversations we have with the women who join this interview study will help us better understand relationships between men and women. You are being asked to be in this study as you were in the main study.

B. What Will Happen In The Interview

We are asking you to take part in an individual interview. The interview will be like a conversation but you will do most of the talking. It will last about one hour. This is a one-time interview. You will be asked questions that do not have right or wrong answers.

To be in this study, you must be 18 to 59 years old. The interview will be audio recorded and a staff person may take notes. We will do this because we want to be sure we get things exactly as you said them rather than what we think we heard you say.

Your name will not be used in the recording, kept in the notes or used in reports. Only the study staff will listen to the tapes and read the notes. During the interview you are free to refuse to answer any question. You can also stop taking part in the interview at any time.

C. Risks

Some questions may make you feel uncomfortable or embarrassed.

D. Benefits

There may be no direct benefit to you but you may enjoy sharing your thoughts and experiences. What you tell us may help us better understand relationships between men and women and ways relationships may affect a woman's chance of getting HIV.

E. How Your Records Will Be Kept Private

We will keep all your private facts and what you tell us in the interview private.

A number code will be used to identify your interview. Your name will not be used. We use the audio recording to make a typed record of what you say. After that, we will destroy the recording. We will not keep the recording for more than one year. Only the people doing this study will be able to listen to your audio recording or see the typed record.

We will protect your typed record with a password. Paper files, like a signed consent form, will be locked in a cabinet and destroyed within five years.

What you tell us will be added to what we hear in other interviews. As we said, we plan to interview about 60 women. Your interview will not be presented alone.

This study has applied for a Federal Certificate of Confidentiality. This means we cannot be forced to give out any information that would identify you.

F. Voluntary Participation

You are free to join the study or not. If you do not join, you will not lose any services that you can get apart from this study. If you decide to join the study, you can choose not to answer any question or stop at any time. In that case too, you will not loose any services that you can get apart from this study.

G. Alternative To Being In The Study

Your alternative is not to be in the study

H. Costs

There is no cost to your for being in this study.

I. Payment

We will give you \$30 [cash or gift certificate] at the end of the interview as a thank you.

K. Questions

If you have questions about this study or if you think you have been harmed as a result of being in this study, you can contact [Local contact person (s), phone number (s) and institution (s)].

If you have questions about your rights as a research subject, you may contact the head of the [Local Institutional Review Board], at [phone number]. You may also contact the office of CDC's Deputy Associate Director for Science at 1-800/584-8814 where you can leave a brief message with your name, phone number, and CDC protocol number #5011 for this project.

J. Agreement

I have read (or someone has read to me) the information above. I have had all my questions answered. I have been given a copy of this form. I agree to be in this study and take part in an individual interview that will be audio taped.

Date

Participant's signature, initials, or alias

Date

Signature of person obtaining consent