

**Nurse Delivered Sexual Risk Reduction Intervention for
HIV-Positive Women in the South**

0920-XXXX

Attachment 7a

Consent-Trial

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Consent Form Trial

University of North Carolina, Chapel Hill

School of Nursing

CONSENT TO PARTICIPATE IN A RESEARCH PROGRAM

**SISTER TO SISTER POSITIVE HOPE PROJECT
STUDY**

**University of North Carolina-Chapel Hill
Sister-to-Sister Positive HOPE
Informed Consent Form**

IRB Study #: 07-1016

Consent Form Version Date: 1-06-08

Title of Study: Reducing Sexual Risk in Southern HIV-Positive Women

Principal Investigator: Catherine Ingram Fogel, PhD, RNC, FAAN

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Nurse Interventionists (2) to be named later

Research Assistants (3) to be named later

CDC-PRB, DHAP, NCHSTP, CCID

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Name of funding source or sponsor:

Federal: The Centers for Disease Control and Prevention

Funding Mechanism: Cooperative Agreement

Funding Number: U01 PS000100-01

FWA Number: FWA00004801

Study Contact telephone number: 919-966-3119

Study Contact email: cfogel@email.unc.edu or nabrown@email.unc.edu

Flesch – Kincaid Reading Level: 7.0

These are some things that we want you to know about research studies

You are being asked to be in a research study. You don't have to be in this study if you do not want to. You may stop being in the study at any time. If you decide to stop, it will not change the way you receive care.

We do research studies to learn new information. This new information may help people in the future. Sometimes good things happen to people who take part in studies, and sometimes things we may not like happen. We will tell you more about these things below.

We will tell you more about this research study in the next part. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who help them, any questions you have about this study at any time.

What is the purpose of this study?

The reason we are doing this study is to learn if a program our research team developed for HIV-positive women living in the South will help HIV-positive women make healthy choices in their lives. You are being asked to be in the study because you are an HIV-positive woman living in the South.

Are there any reasons you should not be considered for this study?

You should not be in the Sister to Sister Positive HOPE study if you are not HIV-positive, under age 18, are planning to get pregnant in the next 3 months, or planning to move out of the area before the next 3 months.

How many people will take part in this study?

If you decide to be in this study, you will be one of approximately 330 women in this research study.

How long will your part in this study last?

After you agree to be in the study you will be asked a number of interview questions that will take about 45 minutes. You will then be randomly assigned to one of two groups.

If you are in Group 1, you will meet with a nurse individually for a 45-minute information talk. Three months later you will be interviewed again. This interview will also take about 45 minutes to complete.

If you are in Group 2, you will be asked to come back 3 months later to be interviewed again. This interview will also take about 45 minutes to complete. Then, after completing the second interview, if you want to you can meet with a nurse individually for a 45 minute health information talk.

What will happen if you choose to be a part of the study?

Our study team has created a program for HIV positive women living in the South. We want to see if this program helps HIV-positive women make healthy choices in their lives. If you decide to participate in this research study, this is what will happen:

First, we will ask you to answer questions about your health, sex life, and drug use behavior, using a secure computer. This computer is secure because only a few people will have a special code to get to the information that you provide. The interview will take about 45 minutes to complete. Then, you will be picked to be in one of two groups. The group you are assigned to is by chance, like flipping a coin.

Group 1:

When you finish answering the questions, you will meet with a nurse by yourself for a 45-minute talk. The nurse will talk to you about healthy living. She will talk to you about how to protect yourself and others from infections you can get through sex. Three months later you will come back and we will ask you the same questions again about your health, sexual life and drug use behavior using a secure computer. This will also take about 45 minutes to complete.

Group 2:

When you finish answering the questions, you will be asked to come back 3 months later. At that time we will ask you the same questions about your health, sexual life, and drug use behavior. This will take about 45 minutes to complete. Then you can meet with a nurse by yourself for a 45-minute talk about healthy living if you want to.

All the meetings will be in a private room in the same place where you are being asked to participate in the study. The meeting with the nurse will be tape-recorded to help with training. Only the UNC and CDC research staff will listen to the tapes.

What are the possible benefits from being in the study?

People may have good things happen to them because they are in research studies. These are called “benefits.” The benefits to you of being in this study may be what you learn from the healthy living session. We believe that this work can help women living with HIV learn ways to take good care of themselves and those they care about. You may also benefit from meeting with the nurse and learning ways to protect you and your partner from infections you can get from sex.

What are the possible risks from being in the study?

Sometimes things happen to people in research studies that may make them feel bad. These are called “risks.” These are the risks of this study: some of the questions you answer on the computer or in the meeting with the nurse may make you feel uneasy or uncomfortable. These things may not happen to you. Things that the researchers do not know about may happen. We respect your right not to answer any questions. Taking part in the study is up to you. You can stop taking part in the study at any time. If you do not want to be in the study, it will not impact your right to services at the **(fill in the blank with the name of the place you are getting this form)**. You should report any problems to the Sister-to-Sister Positive HOPE Study team.

How will the security of your personal information be protected?

We will do everything we can to make sure no one knows you are in this study. To protect your privacy, your name will not be in any report about this study. Our research staff has been trained to keep your information secure. There may be times when federal or state law can make us give them records that could tell them that you were in the study. This is very unlikely, but if we have to do this, The University of North Carolina, Chapel Hill will take all legal steps to protect the security of your personal information. Sometimes, your information may be looked at by the University, research sponsors, or government agencies. This would be done to make sure the quality and safety of the research is the best that it can be. There are also laws that require us to report if you tell us that you are going to hurt yourself or anyone else, or that a child or older person is being hurt. If this happens, we will have to tell someone (for example: local police or the child welfare agency) to protect that person. We will send your interview answers to the CDC, but we will only give them your study ID number. We will not give them your name

The information that you share with us will be kept secure. The survey and tapes will have a study number, not your name. A single sheet will be used to link your name with the study number. Only the Principal Investigator (PI), Project Manager and Research Data Manager will have access to this sheet. This sheet, consent forms, and tapes will be kept in separate locked file drawers. This file drawer will be in the PI’s (Catherine I. Fogel) research office in the School of Nursing at the University of North Carolina, Chapel Hill. The survey answers will be stored in a secure computer in the Principal Investigator’s research office.

You cannot enroll in this study more than once. To keep that from happening, we will keep your name and contact information until 6 months after the end of the study.

Only project staff will have access to information about you, including your name, study number, and contact information. This information will be kept in a secure computer that is different from the one used to record your answers in the Principal Investigator’s office and destroyed 6 months after the end of the study. The tapes and consent form will be destroyed 5 years after the final reports are completed.

Will you get any thing for being in this research study?

If you are in Group 1, you will get \$30 in cash after you complete the first interview and also the

information talk with the nurse. You will get another \$30 in cash after the second interview which will happen 3 months later. You will also get bus passes to help you with transportation.

If you are in Group 2, you will get \$30 in cash after you complete the first interview. You will get another \$30 in cash after the second interview which will happen 3 months later. You will also get bus passes to help you with transportation.

Will it cost you anything to be in the study?

There are no costs for being in the study.

Who should you ask if you have any questions?

You can ask and have answered any questions you may have about this study. If you have questions call Cathie Fogel, the Principal Investigator or Niasha Brown, the Project Manager at the toll free number (866) 619-0007.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research participant you may contact, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu. You do not have to tell them who you are when you call.

Participants Agreement

I agree to be in this research study. I have been given a chance to ask questions. I feel that all of my questions have been answered. I know that being in this study is my choice. I know that after choosing to be in this study, I may leave at any time. I have been told that the discussion will be audio taped.

I have been given a signed copy of this consent form to keep.

Signature of participant

Date

Investigator

Date

