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

0920-XXXX

Attachment 7b

Consent-In-depth Interview

Consent Form In-depth Interview

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

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Study Contact telephone number: 919-966-3119
Study Contact email: cfogel@email.unc.edu or nabrown@email.unc.edu [Author ID1: at Fri Feb 1 14:21:00 2008]
Flesch - Kincaid Reading Level: 7.1

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 answer. 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 research study is to learn if a program our research team created 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 this part of the Sister to Sister Positive HOPE study if you are not willing to talk with one of the interviewers about your experiences as an HIV-positive woman and about Sister to Sister Positive HOPE intervention.

How many people will take part in this study?

If you choose to be in this study, you will be one of about 25-30 women in this research study.

How long will your part in this study last?

After you agree to be in this part of the study you will be asked some questions. This part will take about 45 minutes.

What will happen if you take part in the study?

You will be interviewed by someone on our research team in a private room in the place where you were asked to participate in the first part of the study. The interview will be audio taped. The interview will be about how you became infected, any ways you have tried to lower your risks, your experiences with using protection, and any experiences you may have had when/if you told people about your HIV status. You will also be asked to tell us what you think about the Sister to Sister Positive HOPE intervention.

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 study 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 in your talk may make you feel uneasy or uncomfortable. 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 change your right to services at the (fill in the blank with the name of the place you are getting this form). Not all of these things may happen to you. None of them may happen or things may happen that the researchers don't know about. 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. 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 tell others 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.

The information that you share with us will be kept secure. The interview 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 Principal Investigator'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. 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 receive anything for being in the study?

We will give you $30 in cash and a bus pass when you finish your talk for your time and effort.

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 copy of this consent form to keep.

Signature of participant

Date

Investigator