

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

0920-XXXX

Attachment 3

Screener/Contact Form

Attachment 3a

ID Number:

Public reporting burden of this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; Attn: PRA (0920-XXXX)

Screener Form

Sister to Sister Positive HOPE Project

BEFORE APPROACHING THE POTENTIAL PARTICIPANT VERIFY WITH CLINIC STAFF AND THE PRINCIPAL INVESTIGATOR THAT:

- The potential participant did not participate in the focus group or pilot study
- The potential participant is a resident of NC
- The potential participant does not have severe cognitive impairment

Staff name: _____

Date: _____ Time: _____

Instructions: Read statements in *bold italics* to the potential participant. Write responses directly on this form. Do not write the participant's name or contact information on this form. The participant's ID number must be written on this form and contact information must be recorded separately on the Screener Contact Form.

I. APPROACHING THE POTENTIAL PARTICIPANT

Introduce yourself warmly and professionally:

“Hi, I’m _____ with the Sister to Sister Positive HOPE Project and I would like to talk to you about a research study we are conducting at the University of North Carolina Chapel Hill.

Have we already talked to you about being in this study?

- _____ 1) Yes **Thank you for your time.**
 2) No **Continue reading script.**

Is now a good time to tell you about the project and see if the study might be helpful for you?

- _____ 1) Yes **“Good” – Continue to Section II**

_____ 2) No, this time doesn’t work, but person is interested. **Get her phone number. Ask for a good time to call. Ask if it is okay to leave a message OR give her the study phone number and business card. Document this on the Screener Contact Form.**

When calling the person, read Section II Introducing the Trial Study. If you call and do NOT reach the person, then call again later or leave a message stating **“We are calling from the Sister to Sister Positive HOPE Project because you told us that you might be interested in participating in a research study. Please call us back at (919) 966-3119 or our toll free number 1(866) 619-0007 at your convenience or leave us a message telling us the best time to call you.”** Log this information on the Screener Contact Form.

- _____ 3) Person is not interested in the program. **Thank the person and leave.**

II. INTRODUCING THE TRIAL STUDY

A. “I want to thank you for your interest in our study. First, I’m going to tell you a little bit about the study. Then, if you’re still interested, I’ll ask you some questions to determine if you are eligible to participate in the study.”

“First, about the study: We are a group of nurse researchers from the University of North Carolina Chapel Hill who are working with the Centers for Disease Control and Prevention in Atlanta.”

Screener: Read the description below

B. Study Description

Our research team has developed a program for HIV-positive women living in the South. We want to see whether this program can help HIV-positive women make healthy choices in their lives.

If you decide to participate in our study, this is what will happen. First, we’ll ask you to take a face-to-face interview with an interviewer in a private office. The interview will ask questions about your health, sexual practices, and drug using behaviors, and should last up to

45 minutes. In addition to questions asked by the interviewer you will also be answering some questions using a computer.

After completing the interview, you will either meet with a nurse in the private office for a 45-minute session to talk about healthy living including discussions about how to protect yourself and others from sexually transmitted infections and then be reinterviewed in three months.

OR after completing the first interview you will be interviewed again in three months.

All information you share will be kept secure by project staff to the extent allowed by law. There also are laws that require us to tell others if you tell us that you are going to hurt yourself or a specific person, or that a child or older person is being hurt or abused. In these cases, we will have to tell someone (e.g., local police or the child welfare agency) to protect that person. The meeting with the nurse may be audiotaped so that the project supervisors can listen to how the nurse is doing. The interview, the tape, and notes from the tape will be destroyed at the end of the study. If you do decide to participate in the study, your name will not be attached to any of the information you give us in the interviews. In appreciation for your time and effort we will give you \$30 and a bus pass for your transportation at each interview.

C. "Are you interested in being screened for this study?"

_____ 1) Yes "Good." Go to Section III

_____ 2) No, person is not interested in the program. Skip to Section III - I

III. SCREENING - AFTER THE POTENTIAL PARTICIPANT HAS BEEN TOLD ABOUT THE STUDY

"Do you feel comfortable right now answering a few personal questions so that I can determine whether you are eligible to participate?"

_____ 1) Yes "Good. Let's start with a few brief questions."

_____ 2) Not a good time, but later "Is it okay of us to call you at a different time?"

Get her phone number. Ask for a good time to call. Ask if it is okay to leave a message and ask her how she would like the caller to identify herself. Also give her the study phone number. Document this on the Screener Contact Form.

_____ 3) No, doesn't want to be screened – Skip to Section III – I

BEFORE ASKING SCREENING QUESTIONS:

You don't have to answer any question you don't want to answer, but if you don't answer a question, I might not be able to tell if you are eligible, and then you won't be able to be in the study.

A. What is your HIV status?

- 1) Positive
- 2) Negative-INELIGIBLE ***"I want to thank you for talking with me, but unfortunately, you are not eligible for the study at this time."***
- 3) Don't know

B. "How old are you?" _____ Years old (If under 18, say *"I want to thank you for talking with me, but unfortunately, you are not eligible for the study at this time."* IF ANY COMMUNITY SERVICE RESOURCES ARE AVAILABLE, PROVIDE THEM. THANK THE PERSON AND LEAVE.)

C. "When was the last time you had sex with a man? By sex I mean vaginal sex where a man put his penis in your vagina, anal sex where a man put his penis in your behind (butt), or oral sex where a man put his penis in you mouth."

- _____ 1) Never– **INELIGIBLE** Keep screening.
- _____ 2) More than 90 days ago– **INELIGIBLE** Keep Screening
- _____ 3) 90 days or less

D. "Would you feel comfortable taking a face-to-face interview and having a face-to-face meeting with a nurse that might include discussions about sexuality and drug use?"

- _____ 1) Yes
- _____ 0) No - **INELIGIBLE**

E. "Do you feel comfortable speaking and reading in English?"

- _____ 1) Yes
- _____ 0) No

F. "Do you intend to get pregnant in the next 3 months?"

- _____ 1) Yes - **INELIGIBLE**
- _____ 0) No

G. Is person eligible?

- _____ 1) Yes
- _____ 2) No– doesn't meet study criteria

A) If NO:

THANK YOU

"I want to thank you for talking with me, but unfortunately, you are not eligible for the study at this time. Due to the nature of this research, we're limited in terms of the numbers of

people we can enroll due to our recruitment criteria. IF ANY COMMUNITY SERVICE RESOURCES ARE AVAILABLE, PROVIDE THEM. THANK THE PERSON AND LEAVE.

B) If YES:

"It looks like you are eligible for the study. Are you still interested in participating?"

_____1) Yes– go to question H.

_____2) No– go to question I.

H. Give eligible participants directions to proceed with the study.

"We would like to thank you for helping us with our study. Again, I want to remind you that all of the information that you gave us is secure to the extent permitted by law."

End screening.

IF PERSON REFUSES TO PARTICIPATE:

I. Person decides not to participate at any point: ***"Thank you for taking the time to talk with me today. You don't have to answer the next question if you do not wish, but it would be helpful for us to know why you do not want to participate?"*** IF ANY COMMUNITY SERVICE RESOURCES ARE AVAILABLE, PROVIDE THEM. THANK THE PERSON.

_____1) Not interested in study topic

_____2) Study topic too sensitive/personal

_____3) Scheduling difficulties

_____4) Concerned about personal information security

_____5) Not comfortable participating

_____6) Other: (specify _____)

"Thank you again for your time."

Attachment 3b

Screener Contact Form

Sister to Sister Positive HOPE Project

DATE: _____

NAME: _____

TEL: _____ **ALTERNATE TEL:** _____

OK TO LEAVE REMINDER MESSAGE? Y: _____ **N:** _____

BEST TIME TO REACH: _____

HOW WOULD YOU LIKE FOR US TO IDENTIFY OURSELVES WHEN WE CALL YOU:

Sister to Sister Positive HOPE _____

University of North Carolina at Chapel Hill _____

Research Study _____

Other: _____

CONTACT ACTIVITY

Date Time Contact Type Outcome (scheduled date/time?)

_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

NOTES
