

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

**0920-XXXX**

**Attachment 7**

**Attachment 7a**

**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**

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**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

**UNC-Chapel Hill Department:** Nursing

**UNC-Chapel Hill Phone number:** 966-3590 or 966-3119

**Email Address:** [cfogel@email.unc.edu](mailto:cfogel@email.unc.edu)

**University of North Carolina-Chapel Hill**

David Wohl, MD Co-Investigator

Mark Weaver, PhD, Co-Investigator

Margarete Sandelowski, PhD, RN

Nurse Interventionists (2) to be named later

Research Assistants (3) to be named later

**CDC-PRB, DHAP, NCHSTP, CCID**

Kim Williams, Ph.D., Project Officer

Yuko Mizuno, Ph.D., Co Project Officer

Ann O'Leary, Ph.D., Consultant

Dale Stratford, Ph.D., Consultant

**Consultants**

Loretta Sweet Jemmott, PhD

Lynette Gueits, MPH

**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](mailto:cfogel@email.unc.edu) or [nabrown@email.unc.edu](mailto:nabrown@email.unc.edu)

**Flesch – Kincaid Reading Level:** 7.0

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**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 my 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 your privacy 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 private. 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 your privacy. 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 private. 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 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 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](mailto: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.

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*Signature of participant*

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*Date*

---

*Investigator*

---

*Date*

**Attachment 7b**

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

**UNC-Chapel Hill Department:** Nursing

**UNC-Chapel Hill Phone number:** 966-3590 or 966-3119

**Email Address:** [cfogel@email.unc.edu](mailto:cfogel@email.unc.edu)

**University of North Carolina-Chapel Hill**

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Mark Weaver, PhD, Co-Investigator

Margarete Sandelowski, PhD, RN

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Research Assistants (3) to be named later

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**Consultants**

Loretta Sweet Jemmott, PhD

Lynette Gueits, MPH

**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](mailto:cfogel@email.unc.edu) or [nabrown@email.unc.edu](mailto: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 your privacy 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 private. 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 your privacy. 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 private. 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 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](mailto: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*

---

**Attachment 7c**

Flesch-Kincaid = 8.0

**Recruitment Flyer**

# *Sister to Sister*

positive HOPE

health opportunities for protection empowerment

## *Living Positively with Positive HOPE*

Want to learn how to make healthy choices in your life?

We have a study to help you learn!

If you are in the study, you will meet with a nurse privately at a local community health center. You will learn about staying healthy and reducing your chances of catching or passing on HIV.

If you are in the study, you will be given a maximum of \$60 cash for your time and effort and all day bus passes.

Please call [1-866-619-0007](tel:1-866-619-0007) to find out about the study and find out if you can be in the study.

Sister to Sister Positive HOPE is a research study carried out by The Centers for Disease Control and Prevention and The UNC School of Nursing at Chapel Hill.

Attachment 7d

Flesch-Kincaid = 9.5

Project Business Card

*Sister to Sister*

posi+ive HOPE  
health opportunities for protection empowerment

**1-866-619-0007**  
Catherine I. Fogel, Principal Investigator  
Niasha Brown, Project Manager  
CB# 7460  
Chapel Hill, NC 27599-7460

*Sister to Sister*

posi+ive HOPE  
health opportunities for protection empowerment

**1-866-619-0007**  
Catherine I. Fogel, Principal Investigator  
Niasha Brown, Project Manager  
CB# 7460  
Chapel Hill, NC 27599-7460

*Sister to Sister*

posi+ive HOPE  
health opportunities for protection empowerment

**1-866-619-0007**  
Catherine I. Fogel, Principal Investigator  
Niasha Brown, Project Manager  
CB# 7460  
Chapel Hill, NC 27599-7460

*Sister to Sister*

posi+ive HOPE  
health opportunities for protection empowerment

**1-866-619-0007**  
Catherine I. Fogel, Principal Investigator  
Niasha Brown, Project Manager  
CB# 7460  
Chapel Hill, NC 27599-7460

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posi+ive HOPE  
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**1-866-619-0007**  
Catherine I. Fogel, Principal Investigator  
Niasha Brown, Project Manager  
CB# 7460  
Chapel Hill, NC 27599-7460

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**1-866-619-0007**  
Catherine I. Fogel, Principal Investigator  
Niasha Brown, Project Manager  
CB# 7460  
Chapel Hill, NC 27599-7460

*Sister to Sister*

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**1-866-619-0007**

Catherine I. Fogel, Principal Investigator  
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Chapel Hill, NC 27599-7460

*Sister to Sister*

positive HOPE

health opportunities for protection empowerment

**1-866-619-0007**

Catherine I. Fogel, Principal Investigator  
Niasha Brown, Project Manager  
CB# 7460  
Chapel Hill, NC 27599-7460

**Attachment 7e**

**Recruitment Script - Phone Message**

**Sister to Sister Positive HOPE**

Hello, my name is\_\_\_\_\_. I am a (faculty member/staff member) from the University of North Carolina at Chapel Hill Sister to Sister Positive HOPE program.

I understand that you are interested in learning more about our program.

Please contact our office at either the toll free number 1-866-619-0007 or 919-966-3119.

Thank you.

Attachment 7f

**Appointment Reminder Card**

Flesch-Kincaid = 9.0

*Sister to Sister*

posi+ive HOPE  
health opportunities for protection empowerment

**Next Appointment:** \_\_\_\_\_

**1-866-619-0007**  
CB# 7460  
Chapel Hill, NC 27599-7460

*Sister to Sister*

posi+ive HOPE  
health opportunities for protection empowerment

**Next Appointment:** \_\_\_\_\_

**1-866-619-0007**  
CB# 7460  
Chapel Hill, NC 27599-7460

*Sister to Sister*

posi+ive HOPE  
health opportunities for protection empowerment

**Next Appointment:** \_\_\_\_\_

**1-866-619-0007**  
CB# 7460  
Chapel Hill, NC 27599-7460

*Sister to Sister*

posi+ive HOPE  
health opportunities for protection empowerment

**Next Appointment:** \_\_\_\_\_

**1-866-619-0007**  
CB# 7460  
Chapel Hill, NC 27599-7460

*Sister to Sister*

posi+ive HOPE  
health opportunities for protection empowerment

**Next Appointment:** \_\_\_\_\_

**1-866-619-0007**  
CB# 7460  
Chapel Hill, NC 27599-7460

*Sister to Sister*

posi+ive HOPE  
health opportunities for protection empowerment

**Next Appointment:** \_\_\_\_\_

**1-866-619-0007**  
CB# 7460  
Chapel Hill, NC 27599-7460



## Attachment 7g

### **Appointment Reminder Script - Speaking to Participant**

#### **Sister to Sister Positive HOPE**

Hello, my name is \_\_\_\_\_. I am a (faculty member/staff member) from the University of North Carolina at Chapel Hill Sister to Sister Positive HOPE program.

We have scheduled your appointment for (insert date) at (insert time) at the (Insert location). Is this an OK time for you?

You will receive \$30.00 and a bus passes to thank you for your time and effort.

If you have any questions about the program or if you need to reschedule the time for your appointment, you can call Dr. Fogel at (919) 966-3119.

Thank you again for agreeing to be a part of our program.

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### **Appointment Reminder Script – Leaving Message for Participant**

#### **Sister to Sister Positive HOPE**

Hello, my name is \_\_\_\_\_. I am a (faculty member/staff member) from the University of North Carolina at Chapel Hill.

We wanted to remind (name) that we have scheduled an appointment for (insert date) at (insert time).

If she has any questions or needs to reschedule the time for her appointment, she can call Dr. Fogel at (919) 966-3119.

Thank you.

**Attachment 7h**

**Thank you Letter**

Flesch-Kincaid = 6.8

**NAME**  
**STREET ADDRESS**  
**CITY, STATE, ZIP**

**DATE**

Dear **SUBJECT'S FIRST NAME**,

It was good to meet you the other day. I appreciate your taking the time to talk with me. We will plan to meet with you again on **DATE, TIME**.

We will be in touch closer to that time to confirm the date, so we can make sure that this date and time still work for you. At the end of our next interview, we will be able to give you another \$30 and a bus pass for your time and effort. Please call us at **1-866-216-6326** if your contact information changes, so we can keep in touch.

If you need to contact us at the Sister to Sister Positive HOPE Study for any reason, please feel free to give us a call. If you move or change addresses or telephone numbers, please let us know. You can call toll free at **1-866-619-0007**.

We look forward to seeing you again. Many thanks for your contribution to the project!

Take care,

**YOUR NAME**  
Research Assistant  
Sister to Sister Positive HOPE Study

Attachment 7i

**In-depth Interview Recruitment Script**

**SISTER-TO-SISTER POSITIVE HOPE**

**IN-DEPTH INTERVIEW INTRODUCTION SCRIPT**

Now that you have finished the second Sister-to-Sister Positive HOPE interview, we would like to ask you to take a little more time and talk with us about what it is like to be a woman living with HIV and also your experiences with the Sister-to-Sister positive HOPE study.

If you decide to participate in this part of our study, this is what will happen. You will be interviewed about your becoming infected, any risk reduction efforts you may have used and your experiences with them, and any experiences you may have had when/if you told people about your HIV status. You will also be asked to provide feedback about the Sister to Sister Positive HOPE intervention. This interview will take about 45 minutes and will be taped.

Just like in the other parts of the study, all information you share with us will be kept confidential (private) by the 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. Your interview will be audiotaped so that we can listen while we talk and at the same time make sure we get everything that you tell us. 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.

Just like the other parts of the Sister to Sister Positive HOPE study, we will give you \$30 and a bus pass for your transportation In appreciation for your time and effort.