HIV/AIDS Risk Reduction Interventions for African-American Heterosexual Men

0920-09XX

Attachment 8a
Local IRB Approval – SUNY

SUNY DOWNSTATE Medical Center

University Hospital of Brooklyn
College of Medicine
School of Graduate Studies
College of Nursing
College of Health Related Professions

Institutional Review Board
University Hospital of Brooklyn
Kings County Hospital

Eli A. Friedman, M.D. *Chair*
Morris J. Schoeneman, M.D., *Vice-Chair*, Committee A
Stanley Friedman, M.D., *Vice-Chair*, Committee B

FWA 00003624
Study number 09-047

March 4, 2010

Tracey E. Wilson, PhD
Dept. of Preventive Medicine
Box 1240

RE: APPROVAL OF AMENDMENT to study number 09-047: Barbershops as Behavioral Settings for HIV Prevention Targeting African American Heterosexual Men: Phase 1 (Formative Research) (Centers for Disease Control and Prevention) PS000691

Dear Dr. Wilson:

Your request for amendment to the study listed above was reviewed at the 2/16/2010, meeting of the HSCB/KCHC Institutional Review Board.

The requested amendment involves involves the activation of phase 2 which consists of conducting a 'pre-pilot' test with 9 men and a 'post-pilot' of 80 men in order to assess feasibility, acceptibility and potential impact of the intervention. A new consent form for this phase has been added.

You are granted permission to conduct your study as revised effective immediately. The date for continuing review remains unchanged at 4/7/2010, unless closed before that date.

Please note that any further changes to the study must be promptly reported and approved. Contact the IRB staff (718-270-2680 / fax:718-270-3942 / email:irb@downstate.edu) if you have any questions or require further information.

Sincerely,

Eli A. Friedman, M.D.
Chair

CONSENT FORM

Intervention Pilot test

Arthur Ashe Institute for Urban Health, Inc.

State University of New York, Downstate Medical Center

BARBERSHOP TALK PROJECT

We are asking if you want to be in a research study. This study is for African American men who receive services at barbershops in Central Brooklyn and Flatbush. The purpose of this study is to see whether an HIV prevention program can be used to help reduce HIV risks among men. While we review this form, you may read along.

What you should know about research studies:

- This consent form tells you about the study. It tells you about the purposes, risks, and benefits of this research study.
- You do not have to be in this research study; your participation is voluntary. You can agree to be in the study now and change your mind later.
- There may be risks for being in this study. The risks involves feeling uncomfortable about being asked personal questions. You can refuse to answer any question that you do not want to answer.
- Please read this consent form with care. Ask any questions you have before you make a decision.

1) Why is this research being done?

African American heterosexual men are at higher risk than some other groups of people for different health problems, including HIV. HIV is the virus that causes AIDS. We want to design programs that can help reduce these risks and that can reach African American men. One way to do this is to have HIV prevention in barbershops. We have developed an HIV prevention program that we are testing in barbershops, and are asking men who receive services at barbershops to participate in this testing.

2) Who is doing the study?

Dr. Tracey E. Wilson at SUNY Downstate and Dr. Ruth C. Browne at the Arthur Ashe Institute for Urban Health, Inc. are in charge of this study at this location. About 15-20 people will be in the study at this location; 60-80 people will be in the study overall.

3) You cannot be in this study if you:

- Are younger than 18
- Are more than 45 years old
- Are a woman
- Do not consider yourself as Black or African American
- Are not sexually active
- Have been part of a research study related to drug use or to HIV in the past 12 months
- Participated in the formative or pre-pilot phase of this study

4) What will happen to you if you decide to be in this study?

If you agree to be in this study, you will be participating in a two-part HIV prevention intervention session. We are asking you to complete two study visits. The first study visit will take place either now or in the next few days, and the second one will take place in three months. During the first study visit, you will be asked to answer a series of questions about yourself. Some of these questions will be personal; you have the right not to answer any questions that you do not want to answer. These questions will be asked and answered on the computer. The questions will be asked through a set of headphones and you will press a number or letter on the computer based on your answer. No one will be able to hear the questions or see your answers while you complete these questions except you. A study staff person will show you how to use the computer and will be there to help you if you need. The computer survey will take about twenty minutes. After you answer the questions, our trained study staff will be talking with you individually for about forty-five minutes about ways to protect yourself from HIV. The first study visit will take place at this barbershop. We are studying whether our education program is helpful to people to help them reduce their risk of HIV. We will be audiotaping this intervention session.

During your second study visit, you will be asked to answer a set of questions about yourself. Just like before, these questions will be asked and answered on the computer. The questions will be asked through a set of headphones and you will press a number or letter on the computer based on your answer. No one will be able to hear the questions or see your answers while you complete these questions except you. This will take about twenty minutes. This second study visit will take place either at the barbershop or at SUNY Downstate.

5) What are the possible risks of being in the study?

There are no risks associated with being in this study. However, you may feel uncomfortable about being asked personal questions and talking about sensitive topics at the barbershop. You can refuse to answer any question that you do not want to.

6) What are the possible benefits of being in the study?

There are no medical benefits to being in this study. However, by being in this study, you may learn about important ways to help keep yourself healthy.

7) What are your other choices?

The alternative to being in this study is to not participate.

8) If you have any questions or problems, whom can you call?

If you have any questions about this study or think that you have been injured because of the research, you can call Dr. Tracey Wilson at (718) 270-2105 or Dr. Ruth Browne at (718) 222-5953. Dr. Wilson is with SUNY Downstate Medical Center and Dr. Browne is with the Arthur Ashe Institute of Urban Health, Inc. If you are interested in finding out about the results of this study, you can call either Dr. Wilson or Dr. Browne.

If you have questions about your rights as a research subject, you can call the IRB office at (718) 270-2680.

9) What information do we keep private?

In this study we will keep your personal information confidential. We will hold your identity confidential and all data will be kept in a secure location, in the research office at SUNY Downstate Medical Center. We will not reveal your identity in any publication or presentation of the results of the study. Your name will not be listed on surveys or mentioned during the assessments. However confidentiality cannot be guaranteed; your personal information may be disclosed if required by the Federal Privacy law.

We will be audiotaping the intervention session so that staff will have a way to make sure the project procedures are being implemented as planned. This information will also help us improve future HIV prevention interventions using the barbershop setting. These tapes will be typed up so that we will have a written record of what was said during the session. Your name will not be attached to the tapes or typed up notes. The tapes will be stored in a secure location and will be erased after the study is complete. Only the study investigators working directly with the project will have access to the tapes.

Federal law protects your right to privacy concerning Individually Identifiable Health Information (IIHI). There are certain things you need to know, IIHI is any information from your medical record, or obtained from this study, that can be linked to you, and that refers to your mental or health conditions in the past, the present or the future.

For this study we will create, use or report the following IIHI:

- Information obtained from this study, including information obtained from the consent form. The only identifiable information will be your name on this consent form.

We will not store your consent form with any of the other information that you give us. Therefore, others will not be able to connect your identity with what you have said in the study. Data from the surveys will be transferred to CDC but will not include any information that will identify you directly. The information that you give us will have an identification number on it, instead of your name. Your name and identification number are only linked on a secure, password-protected computer file, which also includes your contact information. Only our study staff will have access to this file. This file will be destroyed after the study is completed.

The researchers (Dr. Tracey E. Wilson, Dr. Michael A. Joseph), their staff and the staff of SUNY Downstate Medical Center (Yolene Gousse), and the Arthur Ashe Institute for Urban Health, Inc. (Dr. Ruth Browne, Dr. Marilyn White) participating in the research will use your protected IIHI for this research study.

We will have to use and report your health information for an indefinite period of time.

We have applied for a Certificate of Confidentiality for this study. This certificate helps researchers protect the privacy of human research participants enrolled in sensitive research. With this certificate, study staff cannot be forced to give any information about your identity and participation to anyone not connected with this research, including any federal, state or local court. The study staff will use the certificate to resist any demands for information that would identify you, except as explained below. The Certificate of Confidentiality does not prevent you from voluntarily giving information about yourself of involvement in this study. If you give written consent for an insurer, health care provider, or other person to receive research information, then we may not use the Certificate to withhold that information

Despite the Certificate, the study staff will disclose to the proper authorities, without your consent, instances in which they learn of possible child abuse and/or neglect, or risk of purposeful harm to yourself of others. Even though the study staff will do everything possible to protect your identity, participation in research may result in loss of privacy. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or federal government-related projects.

You can withdraw your authorization for the use or reporting of your IIHI. You have to write to us to withdraw (Tracey E. Wilson, PhD, Department of Community Health Sciences,SUNY Downstate Medical Center, Box 1240, 450 Clarkson Avenue, Brooklyn, NY 11203). If you withdraw we will stop collecting and accessing your IIHI, but we will collect and report any adverse event (bad effect) that you had in the study. Your IIHI collected before you withdraw your authorization will still be used and reported.

If you withdraw your authorization you can no longer be in the study.

HSCB/KCHC IRB
PROTOCOL # 09-047
APPROVED 3-4-10 TO 4-7-10

10) Can your being in the study end early?

Being in this study is voluntary. You can agree to be in the study now and change your mind later. There are no consequences to you if you decide to quit the study. If you want to quit the study, you should talk to Tracey E. Wilson or one of the study staff members.

Also, the sponsor of the study may end the study early.

11) What else do you need to know?

When you complete the first study visit, we will give you ten dollars cash, plus a twenty dollar gift certificate for a haircut. When you complete the second study visit, we will give you ten dollars cash, plus a twenty dollar gift certificate. If you do not show up for the second study visit, you will keep what we have already given you, but we will not provide the cash or gift certificate for the second study visit. You may keep what we have already given you, even if you decide to quit the study.

For the follow-up assessment, we will provide you with a metrocard to cover the costs of getting to and from the study. If public transportation is not convenient, we will give you the additional money for getting to and from the study, if you give us a dated receipt.

If you accept money or a gift certificate for being in the study, we may have to provide some information about you to professional auditors. This would be done for federal audit and reporting requirements. If you earn $600 or more in a year as a research subject, you may have to pay taxes on that money.

We will give you a copy of this consent form to keep.

12) Subject Consent

By signing this consent form you accept that you read this form, or had it read to you. We will give you a copy of this form.

_____	_____	_____
Signature of Subject (or Legal Guardian)	Date	Print name
_____	_____	_____
Signature of Witness	Date	Print name

HSCB/KCHC IRB
PROTOCOL # 09-047
APPROVED 3-4-10 TO 4-7-10

CONSENT FORM

Pre-Pilot Intervention Testing

Arthur Ashe Institute for Urban Health, Inc.
State University of New York, Downstate Medical Center
Centers for Disease Control and Prevention

BARBERSHOP TALK PROJECT

We are asking if you want to be in a research study. This study is for African American men who receive services at barbershops in Central Brooklyn and Flatbush. While we read you this form, you may read along.

What you should know about research studies:

- This consent form tells you about the study. It tells you about the purposes, risks, and benefits of this research study.
- You do not have to be in this research study; your participation is voluntary. You can agree to be in the study now and change your mind later.
- There may be risk for being in this study. The risk involves feeling uncomfortable about being asked personal questions. You can refuse to answer any question that you do not want to.
- Please read this consent form with care. Ask any questions you have before you make a decision.

1) Why is this research being done?

African American heterosexual men are at higher risk than some other groups of people for different health problems, including HIV. HIV is the virus that causes AIDS. We want to design programs that can help reduce these risks and that can reach African American men. One way to do this is to have HIV prevention in barbershops. We have developed an HIV prevention program that we would like to place in barbershops, and are asking men who receive services at barbershops to tell us their thoughts about the program.

2) Who is doing the study?

Dr. Tracey E. Wilson at SUNY Downstate and Dr. Ruth C. Browne at the Arthur Ashe Institute for Urban Health, Inc. are in charge of this study at this location. About 9 people will be in the study.

3) You cannot be in this study if you:

- Are younger than 18
- Are more than 45 years old
- Are a woman
- Do not consider yourself as Black or African American
- Are not sexually active
- Participated in the formative phase of this study

4) What will happen to you if you decide to be in this study?

If you agree to be in this study, you will be participating in a single session HIV prevention intervention where our trained study staff will be talking with you individually for about forty-five minutes about ways to protect yourself from HIV. This session will take place in the barbershop. We are studying whether our education program is helpful to people to help them reduce their risk of HIV. We will be audiotaping this intervention session. Immediately after the intervention session has been completed our study staff will also be asking you a series of questions about your thoughts on the education program. We will be taking notes about what you tell us during this time. These questions will take another thirty minutes to complete.

5) What are the possible risks of being in the study?

There are no risks associated with being in this study. However, you may feel uncomfortable about being asked personal questions and talking about sensitive topics at the barbershop. You can refuse to answer any question that you do not want to.

6) What are the possible benefits of being in the study?

There are no medical benefits to being in this study. However, your responses may help us to create programs that could help improve the health of men in your community.

7) What are your other choices?

The alternative to being in this study is to not participate.

8) If you have any questions or problems, whom can you call?

If you have any questions about this study or think that you have been injured because of the research, you can call Dr. Tracey Wilson at (718) 270-2105 or Dr. Ruth Browne at (718) 222-5953. Dr. Wilson is with SUNY Downstate Medical Center and Dr. Browne is with the Arthur Ashe Institute of Urban Health, Inc.
If you have questions about your rights as a research subject, you can call the IRB office at (718) 270-2680.

9) What information do we keep private?

In this study we will keep your personal information confidential. We will hold your identity confidential and all data will be kept in a secure, limited access location. We will not reveal your identity in any publication or presentation of the results of the study. Your name will not be listed on surveys or mentioned during the interview. However confidentiality cannot be guaranteed; your personal information may be disclosed if so required by the Federal Privacy law.

We will be audiotaping the intervention session so that staff will have a way to make sure the project procedures are being implemented as planned. This information will also help us improve future HIV prevention interventions using the barbershop setting. These tapes will be typed up so that we will have a written record of what was said during the session. Your name will not be attached to the tapes or typed up notes. The tapes will be stored in a secure location and will be erased after the study is complete. Only the study investigators working directly with the project will have access to the tapes.

Federal law protects your right to privacy concerning Individually Identifiable Health Information (IIHI). There are certain things you need to know, IIHI is any information from your medical record, or obtained from this study, that can be linked to you, and that refers to your mental or health conditions in the past, the present or the future.

For this study we will create, use or report the following IIHI:

- Information obtained from this study, including information obtained from the consent form. The only identifiable information will be your name on this consent form. We will not store your consent form with any of the other information that you give us. Therefore, others will not be able to connect your identity with what you have said in the study.
- The information that you give us will have an identification number on it, instead of your name. Your name and identification number are only linked on a secure, password-protected computer file, which also includes your contact information. Only our study staff will have access to this file. This file will be destroyed after the study is completed.

The researchers (Dr. Tracey E. Wilson, Dr. Michael A. Joseph), their staff and the staff of SUNY Downstate Medical Center (Yolene Gousse), and the Arthur Ashe Institute for

Urban Health, Inc. (Dr. Ruth Browne, Dr. Marilyn White) participating in the research will use your protected IIHI for this research study.

Your IIHI will be shared with the following persons or agencies for purposes related to the conduct of the research:

- The Institutional Review Board of SUNY Downstate Medical Center, the applicable DMC Officials and the federal Office for Human Research Protections.

We have applied for a Certificate of Confidentiality for this study. This certificate helps researchers protect the privacy of human research participants enrolled in sensitive research. With this certificate, study staff cannot be forced to give any information about your identity and participation to anyone not connected with this research, including any federal, state or local court. The study staff will use the certificate to resist any demands for information that would identify you, except as explained below. The Certificate of Confidentiality does not prevent you from voluntarily giving information about yourself of involvement in this study. If you give written consent for an insurer, health care provider, or other person to receive research information, then we may not use the Certificate to withhold that information

Despite the Certificate, the study staff will disclose to the proper authorities, without your consent, instances in which they learn of possible child abuse and/or neglect, or risk of purposeful harm to yourself of others. Even though the study staff will do everything possible to protect your identity, participation in research may result in loss of privacy. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or federal government-related projects.

You can withdraw your authorization for the use or reporting of your IIHI. You have to write to us to withdraw (Tracey E. Wilson, PhD, SUNY Downstate Medical Center, Box 1240, 450 Clarkson Avenue, Brooklyn, NY 11203). If you withdraw we will stop collecting and accessing your IIHI, but we will collect and report any adverse event (bad effect) that you had in the study. Your IIHI collected before you withdraw your authorization will still be used and reported.

If you withdraw your authorization you can no longer be in the study.

10) Can your being in the study end early?

Being in this study is voluntary. You can agree to be in the study now and change your mind later. If you want to quit the study, you should talk to Tracey E. Wilson or one of the study staff members.
Also, the sponsor of the study may end the study early.

11) What else do you need to know?

We will give you ten dollars cash, plus a twenty dollar gift certificate for a haircut when you come for the study visit, even if you decide to withdraw or quit the study. If you accept money or a gift certificate for being in the study, we may have to provide some information about you to professional auditors. This would be done for federal audit and reporting requirements. If you earn $600 or more in a year as a research subject, you may have to pay taxes on that money.

We will give you a copy of this consent form to keep.

12) Subject Consent

By signing this consent form you accept that you read this form, or had it read to you. We will give you a copy of this form.

Signature of Subject (or Legal Guardian)	Date	Print name
Signature of Witness	Date	Print name

HSCB/KCHC IRB
PROTOCOL # 09-047
APPROVED 3-4-10 TO 4-7-10