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

0920-10CM

Attachment 4b

Consent Forms - NYBC

CONSENT TO PARTICIPATE IN PILOT TEST EVALUATION

New York Blood Center. New York Academy of Medicine and New York University
STRAIGHT TALK Project

(Flesch-Kincaid Grade Level 6.9)

Principal Investigator: Beryl A. Koblin, Ph.D., New York Blood Center
Phone Number: (212) 570-3105

A. Purpose

STRAIGHT TALK is a research project to help make new ways to prevent HIV. The research is with African American men who have sex only with women. Four groups are doing the research. The groups are The New York Blood Center, The New York Academy of Medicine, New York University and the Centers for Disease Control and Prevention (CDC). We hope to learn if a new program can help African American men avoid getting HIV. About 50 men in New York will take part in this study.

B. What will happen

If you agree to be in this research, you will be asked to:

1. Take a 30-45 minute survey on a computer. You will be asked questions about your age, housing and other characteristics. You will also be asked about sex, types of sex partners, drug and alcohol use, HIV testing history and other issues about HIV. You will be asked to give us information about how to find you so that we can remind you of your next visit.

2. Be in a 2 hour group for 4 times with up to 9 other men. We will give you an appointment to come back in the near future. At that visit, you and up to 9 other men will take part in a group discussion. The group will meet 4 times, about once every week for 4 weeks. The group will be led by two group leaders. You will participate in activities that focus on HIV risk among African-American men who have sex only with women. Before the group begins, you will be asked to agree out loud that you will keep private any personal information talked about during the group.

3. Come at the scheduled time for the group. We may ask you to re-schedule if:
- you come after there are already 10 men here for the group,
- there are not enough other participants, or
- you are late by more than 15 to 20 minutes

4. Return to our study site about three months after that last session. This visit will also last about 1 hour. You will be asked questions that are like the ones you answered at your first visit. You can also talk with a counselor for any referrals, if you need it.

5. The groups will be audiotape recorded. The group will be watched by a staff member and note taker who will sit in the room. They will be taking notes about what was talked about in the group. Tapes are made so that project staff can later review carefully what was talked about during the group.

C. Privacy

The staff will keep your information private to the point allowed by law. We cannot promise complete privacy. To protect your privacy, we will give you a study ID number. Our staff will not talk about personal information about you in the groups. We will send your survey answers to the CDC. We will only give them your study ID number. We will not give CDC your name. Also, we have applied for a Certificate of Confidentiality from the U.S. Government. This certificate means that we cannot be forced to tell people who are not involved with this study, such as the court system, about your taking part in this study. We will tell you if we get this Certificate of Confidentiality.

Your name will not be on any information about this study. Any contact information for you will be kept in a locked file at the project office.

All notes and audio tapes will be locked in a cabinet. Only study staff has access to these items during the project.

Audio tapes will be destroyed after they have been listened to by project staff and once the study has finished. Tapes will never be kept for longer than 24 months after the study ends.

D. Exceptions to Privacy

1) If you tell us that you are planning to cause serious harm to yourself or others, study staff will have to break privacy.

2) Abuse of a child by a parent or someone legally responsible for a child must be reported to child welfare services.

E. Risks and Discomforts

Questions on the survey may make you feel uneasy or embarrassed. If there are questions you do
not want to answer, you do not have to do so.

The groups will involve talking about personal and sensitive issues. This will include sex behavior and possible drug and alcohol use. Talking about these issues could make you feel uneasy or embarrassed. Taking part may involve sharing these personal experiences with others. If there are discussions that you do not want to take part in, or questions you do not want to answer, you do not have to do so.

Being in a group involves a loss of privacy. Our study staff will honor your privacy. This means that our staff will not tell others what you have said in the group. However, we cannot make sure that the other men will keep everything private. We will take the following steps:
a. Staff will not tell anyone that you are someone who was in the study.
b. Group leaders will ask the group to keep private everything that was talked about in the group.
c. The importance of privacy will be talked about with everyone at the start of the group.
d. The group will be asked to use first names or your name of choice only.

F. Benefits
There are no direct benefits to you for taking part in this study. Your taking part in this study may help to make new ways to prevent HIV.

G. Costs
There will be no costs to you for taking part in this study other than your time.

H. Alternatives to taking part in the study
There are other programs and research about ways to prevent HIV in the city. If you do not want to take part in this study, we can tell you about these other programs or studies.

I. Reimbursement
You will get $25 cash for the survey. You will get $25 cash for taking part in each group session. A two-way Metro Card will be given to you at the end of each visit. This is for your time and travel costs. You will also get $40 cash for the visit that occurs 3 months after the group sessions.

You will receive $15 in cash and a two-way Metro Card and we will reschedule your appointment if:

a. you arrive after there are already 10 men here for the group OR
b. there are not enough other participants (less than 5 men)

If you are too late to a study visit or the first group session to do all parts of that visit (about 15 minutes), you may be asked to reschedule. If you are asked to reschedule, you will not do any part of the first visit and will not be reimbursed.

J. Asking you to leave the study without your Consent
You may be asked to leave the study and told about other resources if you disrupt the group too much.

K. Taking part and staying in the study is up to you
Your taking part in this research study is up to you. Whether or not you take part will not affect your right to health care or other services. You are not giving up any legal claims or rights because you are taking part in this study. If you do decide to take part, you are free to stop taking part at any time. If you stop, there is no penalty or loss of health care

or other services.

L. Injury Statement
It is very unlikely that you will be harmed by being in this study. If you are, we will send you to a nearby hospital for emergency care. We will also tell you about a place for other medical care, if you need it. However, the New York Blood Center does not pay for this care. If you sign this form, it does not mean that you are giving up any legal rights to be paid for harm that comes from being in this study. For more information about this, you may contact the Principal Investigator listed in this form.

M. Questions
If you ever have questions or problems about this study or in case of study-related injuries, you should contact: Beryl A. Koblin, Ph.D. at (212)-570-3105.

If you have questions about your rights as a research participant, or problems or concerns about how you are being treated in this study, you may speak with an institutional representative who is not part of this study. Please call the New York Blood Center Institutional Review Board (IRB) Administrator, telephone number (212) 570-3038.

You may also call the New York Academy of Medicine:
Institutional Review Board (Monday through Friday between 9:00 and 5:00) at 212-822-7287 (collect).
You may also write them:
The Institutional Review Board
New York Academy of Medicine
1216 Fifth Avenue--6th Floor
New York, NY 10029.

For questions about your rights as a research participant, you may also contact the New York University Committee on Activities Involving Human Subjects, New York University, 665 Broadway, Suite 804, New York, NY 10012 at 212-998-4808 or ask.humansubjects@nyu.edu

N. Consent
I have talked to _____ about the survey, group sessions and follow-up visit. My questions have been answered. I have been told that the groups will be audio taped and that project staff will listen to it. The project staff will also watch while members of the group talk. It is up to me to take part in this study. I am free to not join the study. I am free to stop being in it at any time. I will not be penalized now or in the future if I decide to leave the study or refuse to answer any question(s). I have been given a copy of this consent form to keep.

_____

_____
Name of Study Volunteer Signature of Study Volunteer
Date

_____

Name of Investigator/Person Obtaining Informed Consent | Signature | Date

This consent form is only valid if it carries the IRB approval stamp with current dates.