Request for Sub-collection Under the Approved Generic ICR: Formative Research and Tool Development

OMB No. 0920-0840, Expiration 31 January 2013

Minority HIV/AIDS Research Initiative (MARI) Project: Sexual risk-taking among young black men who have sex with men: exploring the social and situational contexts of HIV risk, prevention, and treatment (BROTHERS CONNECT STUDY)

Attachment 2. Consent Forms

Consent form for cross-sectional survey (Flesch-Kincaid Reading Level = 7.9)

Information on Research

Invitation to take part in the study

You are invited to be part of the Brothers Connect Study. We are asking you because you are a young, Black man (18-30 yrs old) who reported having sex with other men. A total of 250 men will be a part of this study. All the men will be from New York City.

In order for you to decide if you want to be in the study, we will explain the risks and benefits. This consent form tells you more about the Brothers Connect Study. A member of the research team will talk more about these details with you. During this talk, the research team member will go over all parts of this study. We will tell you why it's being done, the steps, and any risks and benefits. Once you understand the study, you will be asked if you wish to take part. If so, you will be asked to sign this form.

Taking part in the study

If you agree to be a part of this study, you will be asked to tell us about yourself, the way you feel about certain behaviors and your beliefs by taking an internet survey. The survey will be given in a quiet, private office.

Before you take the survey, a member of the research team will meet with you in a private office to speak with you about the survey for 10 minutes. During these 10 minutes, you will get more information about the survey, as well as another 8-week study that you will be invited to be a part of. We will answer any questions you may have.

This survey will ask you to give details about yourself, such as your age, education, and income. It will also ask about any sexual and substance use behaviors. You will also be asked questions about experiences that you may have had when you were younger. We will ask questions about the way you feel about certain behaviors, your ideas and health. The survey will take about one and a half hours to finish. After finishing the survey, you will be paid \$30 for your time. You will also get \$4 for bus or subway costs.

Risks

Some of questions you will be asked in the survey are touchy. You may feel uneasy when asked to answer these questions. You may refuse to answer any question you do not wish to answer. Also, you have the right to leave the study at any time.

If at any time you feel anxious because of this study, you may ask for counseling services. Study staff members will give you information of places where you can get services. If staff members

believe you may benefit from getting counseling or other services, we may also give you the information to these services. You may also seek any health services on your own outside of the research study. Getting any of these services will not change your ability to be a part of the study.

Benefits

The information that you provide may be useful in helping health workers develop programs for young Black men.

Other options

You can choose not to take part in this study.

Privacy

Any information that you give will stay safe. This information can only be made public if you agree to do so, or as required by federal and New York state law. Examples of information that we must report are abuse of a child or elderly person, or any plans to harm yourself or others. In our study, a code number will label you. Only our staff will be able to link this code number to your name. All information you give will be kept in locked file cabinets in study offices at Columbia. Also, all information will be stored on computers that need passwords to open. When the results of the research are in print or talked about, your identity will not be made public.

Also, a Certificate of Confidentiality (CoC) given by the Centers for Disease Control and Prevention (CDC), in the U.S. Department of Health and Human Services protect researchers taking part in this study from being forced to tell people who are not a part of the study about you. But, information about abuse of a child or elderly person, or any plans to harm yourself or others will be reported.

This does not stop you or your family from giving information about you or this research. If you are going to talk about this study with your family, you should make sure that they can keep it private.

Staff from the Columbia University Medical Center Institutional Review Board (IRB) may search study records during reviews. The IRB is a part of Columbia University Medical Center that looks over, approves and monitors research on human beings. Anyone who looks over study records have to keep all information private. Also, researchers from the Centers for Disease Control & Prevention (CDC) may see study records. In all cases, researchers from the CDC will keep all information private.

Reward

You will receive \$30 for finishing the survey. You will also receive \$4 to cover the costs of using a subway or bus to get to and from the study offices.

Additional Costs

There are no costs to you for taking part in the study.

Your Rights

You have rights as a research participant. You are free to choose not to be a part of this study. If you do choose to take part, you are free to leave this study at any time. You are also free to refuse to answer any questions in the survey. If you choose not to take part or leave, it will not harm your relationship with your health providers or with Columbia University.

More Information

If you have any more questions about this project or if you have a research-related problem, you may get in touch with the Principal Investigator, Dr. Patrick Wilson at (212) 305-1852. If you have any questions about your rights as a research subject, you may get in touch with the Columbia University IRB at (212) 870-5883.

Consent form for longitudinal sex diary survey (Flesch-Kincaid Reading Level = 7.8)

Information on Research

Invitation to take part in the study

You are invited to be part of the Brothers Connect Study. We are asking you because you are a young, Black man (18-30 yrs old) who reported having sex with other men. A total of 150 men will be a part of this study. All the men will be from New York City.

In order for you to decide if you want to be in the study, we will explain the risks and benefits. This consent form tells you more about the study. A member of the research team will talk more about these details with you. During this talk, the staff member will go over all parts of this study. We will tell you why it's being done, the steps, and any risks and benefits. Once you understand the study, you will be asked if you wish to take part. If so, you will be asked to sign this form.

Taking part in the study

If you agree to be a part of this study, you will be asked to log on to a website on a weekly basis to take other surveys between today (the day of your first survey if you decide to take part) and the last survey, which will take place about 8 weeks from today. You are invited to come back to the research offices to finish your weekly surveys, but you can also finish them from home, the library or any computer with internet.

More details about taking part in the study are as follows:

- 1. Before you take the first survey, a member of the research team will meet with you in a private office to speak with you about the survey for 10 minutes. During these 10 minutes, you will get more information about the 8-week survey. The staff member will show you how to log into the website to do weekly surveys and how to get around the site. This will also be in writing. You will also be given a password and a login name. After this, you will be asked to take your first weekly survey in the quiet office. This survey will ask you to give details about any sexual and substance use behaviors that you may have done over the past week. The survey will take about 15 minutes to finish. After finishing the online survey, you will be paid \$10 for your time.
- 2. You will be asked to login to the website once a week, on the same day, to take the same short survey. You will get emails each week to tell you to login to the website and take your survey. Your information about which survey week you are starting (i.e., week 2, week 3, etc.) will be shown when you log on to the website. Each survey should take about 10-15 minutes to finish. If you cannot finish the survey on the spot, you can log off the website at any time and go back to the survey at a later time. Please note, because the online survey asks you questions that are touchy, it's better to take the surveys using a

home computer, and not a computer used by others. Also, you can come to the study offices anytime to take your weekly survey in private.

- 3. Each time you finish a survey you will get \$10. If you finish the survey at the research offices, or come into the offices after finishing one or more weekly surveys, you will be paid in person. You may also choose to "bank" your payments to get them all at once at the end of the study, or as needed. You can get banked payments when you come to the research office. You may also choose to have a check or gift card in the amount of your banked payment(s) mailed to you.
- 4. After 8 weeks pass from your first survey, you will be asked to come back to the research office to finish your last (week 8) survey. After finishing the survey, you will be asked to meet with a staff member to talk about your experiences while in the study. If you allow it, the staff member may take notes from the talk about your experiences. The last survey and meeting will take 20 minutes to finish. You will receive \$10 for finishing the last survey, as well as all "banked" payment from past surveys. If you finish all 8 weekly surveys, you will also get an extra payment of \$20.

Risks

Some of questions you will be asked in survey are very touchy. You may feel uneasy when asked to answer questions about your sexual behavior, substance use, feelings and experiences, or other touchy topics. You may refuse to answer any question you feel uneasy answering. Also, you have the right to leave the study at any time.

If at any time you feel anxious because of this study, you may ask for counseling services. Staff members will give you information of places where you can get services. If staff members think that it will do you good by getting counseling or other services, we may also give you the information to these services. You may also seek any health services on your own outside of the study. Getting any of these services will not hurt your taking part in the study.

Benefits

The information that you give may be useful in helping health workers plan programs for young Black men.

Other options

You can choose not to take part in this study.

Privacy

Any information that you give will stay safe. This information can only be made public if you agree to do so, or as required by federal and New York state law. Examples of information that we must report are abuse of a child or elderly person, or any plans to harm yourself or others. In our study, a code number will label you. Only our staff will be able to link this code number to your name. All information you give will be kept in locked file cabinets in study offices at Columbia. Also, all information will be stored on computers that need passwords to open. When the results of the research are in print or talked about, your identity will not be made public.

Also, a Certificate of Confidentiality (CoC) given by the Centers for Disease Control and Prevention (CDC), in the U.S. Department of Health and Human Services protect researchers taking part in this study from being forced to tell people who are not a part of the study about you. But, information about abuse of a child or elderly person, or any plans to harm yourself or others will be reported.

This does not stop you or your family from giving information about you or this research. If you are going to talk about this study with your family, you should make sure that they can keep it private.

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Reward

You will be paid \$10 for each weekly survey that you finish. If you finish all 8 weekly surveys, you will get an extra \$20. The last pay at the end for finishing all weekly surveys is \$100. You will also get \$4 to cover the costs of using a subway or bus to get to and from the study offices each time that you come in.

Other Options

There are no costs to you for taking part in the study.

Your Rights

You have rights as a person taking part in research. You are free to choose not to be a part of this study. If you do choose to take part, you are free to leave this study at any time. You are also free to refuse to answer any questions in the survey. If you choose not to take part or leave, it will not harm your relationship with your health providers or with Columbia University.

More Information

If you have any more questions about this project or if you have a research-related problem, you may get in touch with the Principal Investigator, Dr. Patrick Wilson at (212) 305-1852. If you have any questions about your rights as a research subject, you may get in touch with the Columbia University IRB at (212) 870-5883.

Consent form for in-depth interview (Flesch-Kincaid Reading Level = 8.0)

Information on Research

Invitation to Participate

You are invited to be part of the Brothers Connect Study. We are asking you because you are a young, Black man (18-30 yrs old) who reported having sex with other men. A total of 30 men will be a part of this study. All the men will be from New York City.

In order for you to decide if you want to be in the study, we will explain the risks and benefits. This consent form tells you more about the study. A member of the research team will talk more about these details with you. During this talk, the staff member will go over all parts of this study. We will tell you why it's being done, the steps, and any risks and benefits. Once you understand the study, you will be asked if you wish to take part. If so, you will be asked to sign this form.

Taking part in the study

If you agree to be a part of this study, you will be asked to take part in a 90 minute interview. You will be asked to talk about yourself, and to talk about your past and current experiences. Also, you will be asked to talk about your sexual and substance use behaviors over time, what you went through with family and people who took care of you and other major things that took place. You will also be asked about your past and current experiences in getting healthcare. If you agree, the interview will be taped.

Risks

Some of questions you will be asked in survey are very touchy. You may feel uneasy when asked to answer questions about your sexual behavior, substance use, feelings and experiences, or other touchy topics. You may refuse to answer any question you feel uneasy answering. Also, you have the right to leave the study at any time.

If at any time you feel anxious because of this study, you may ask for counseling services. Staff members will give you information of places where you can get services. If staff members think that it will do you good by getting counseling or other services, we may also give you the information to these services. You may also seek any health services on your own outside of the study. Getting any of these services will not hurt your taking part in the study.

Benefits

The information that you give may be useful in helping health workers plan programs for young Black men.

Other options

You can choose not to take part in this study.

Privacy

Any information that you give will stay safe. This information can only be made public if you agree to do so, or as required by federal and New York state law. Examples of information that we must report are abuse of a child or elderly person, or any plans to harm yourself or others. In our study, a code number will label you. Only our staff will be able to link this code number to your name. All information you give will be kept in locked file cabinets in study offices at Columbia. Also, all information will be stored on computers that need passwords to open. When the results of the research are in print or talked about, your identity will not be made public.

Also, a Certificate of Confidentiality (CoC) given by the Centers for Disease Control and Prevention (CDC), in the U.S. Department of Health and Human Services protect researchers taking part in this study from being forced to tell people who are not a part of the study about you. But, information about abuse of a child or elderly person, or any plans to harm yourself or others will be reported.

This does not stop you or your family from giving information about you or this research. If you are going to talk about this study with your family, you should make sure that they can keep it private.

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Reward

You will be paid \$40 for taking part in the interview. You will also get \$4 to cover the costs of using a subway or bus to get to and from the study offices each time that you come in.

Other Options

There are no costs to you for taking part in the study.

Your Rights

You have rights as a research participant. You are free to choose not to be a part of this study. If you do choose to take part, you are free to leave this study at any time. You are also free to refuse to answer any questions in the survey. If you choose not to take part or leave, it will not harm your relationship with your health providers or with Columbia University.

More Information

If you have any more questions about this project or if you have a research-related problem, you may get in touch with the Principal Investigator, Dr. Patrick Wilson at (212) 305-1852. If you have any questions about your rights as a research subject, you may get in touch with the Columbia University IRB at (212) 870-5883.