Attachment 13 Assent/Consent Forms

Key Informant Consent Form to Be Used When Providing a Token Of Appreciation Is Not Appropriate

English Version; Grade Reading Level by Flesch-Kincaid Method: 8.1

HIV Behavioral Surveillance for Young Men Who Have Sex with Men Key Informant Consent Form

A. Purpose

The [**Agency Name**] and the Centers for Disease Control and Prevention (CDC) are planning a study of young men (between 13 and 17 years of age) who may be at risk for HIV infection, and who will be asked to take an HIV test. The reason for this interview is to learn about the best way to do this future study. We are asking you to participate in this interview because you may be able to give us with ideas about the future study.

B. Procedures

If you agree to be interviewed, this is what will happen.

1. During the interview, a staff member will ask you questions about the following issues:
   a. Ways to encourage young men to take the survey;
   b. Names of places young gay, bisexual, and/or other young men who have sex with men visit or social organizations they belong to;
   c. Reasons young men might not want to take an HIV test, and ways to encourage them to do so;
   d. The types of questions that would be important for us to ask so we can understand sexual behavior in gay, bisexual, and/or other young men who have sex with men.

2. This focus group will not be audio- or video-taped.

3. You can refuse to answer a question at any time. If you do not answer a question or want to end the interview, there will not be any penalty to you. No one except the study staff at [**Agency Name**] will be allowed to see the information you provide to us.

4. The interview is anonymous. Your name will not be attached to your responses.

C. Risks

There are no physical risks to you by participating in this interview. No one will ask about your own behaviors, and you should not share this information during your interview.

D. Benefits

There are no direct benefits to you by being in this interview. The information you give us may help us have a better future study.

E. Compensation

You will not be paid for the time you spend taking part in the interview.

F. Persons to Contact

This study is run by: [*name of principal investigator and phone number*]. You may call [him/her] with any questions about being interviewed.

If you have questions about your rights as a participant or if you feel that you have been harmed, contact [*IRB committee or contact name and phone number*].

G. Confidentiality Statement

What you tell us is confidential. No one except the study staff at [**Agency Name**] and CDC will be allowed to see your comments, except as otherwise required by law. Those allowed to see your comments will not be able to tell that they are your comments because they will be given a summary of comments made by all the people we interview, without names included.

H. Right to Refuse or Withdraw

You may choose not to do this interview without any penalty. You have the right to refuse to answer any questions. You can end the interview at any time you want.

I. Agreement

Do you have any questions?

Interviewer: Answer the participant's questions about the interview before proceeding to the next question.

You have read or had read to you the explanation of this study, you have been given a copy of this form, the opportunity to discuss any questions that you might have and the right to refuse participation. I am going to ask for your consent to participate in this interview. By saying yes, you agree to participate in the interview. Do you agree to take part in the interview?

Date: _____ Interviewer initials in box confirm affirmative consent

I have fully explained to the participant the nature and purpose of the procedures described above and the risks involved in its performance. I have asked if any questions have arisen regarding the procedures and have answered these questions to the best of my ability.

Date: _____ Signature of interviewer: _____

Key Informant Assent/Consent Form to Be Used When Providing a Token of Appreciation for Participation is Appropriate

English Version; Grade Reading Level by Flesch-Kincaid Method: 8.0

HIV Behavioral Surveillance for Young Men Who Have Sex with Men
Key Informant Assent/Consent Form

A. Purpose

The [**Agency Name**] and the Centers for Disease Control and Prevention (CDC) are planning a study of young men (between 13 and 17 years of age) who may be at risk for HIV infection, and who will be asked to take an HIV test. The reason for this interview is to learn about the best way to do this future study. We are asking you to participate in this interview because you may be able to give us with ideas about the future study.

B. Procedures

If you agree to be interviewed, this is what will happen.

1. During the interview, a staff member will ask you questions about the following
    a. Ways to encourage young men to take the survey;
    b. Names of places young gay, bisexual, and/or other young men who have sex with men visit or social organizations they belong to;
    c. Reasons young men might not want to take an HIV test, and ways to encourage them to do so;
    d. The types of questions that would be important for us to ask so we can understand sexual behavior in gay, bisexual, and/or other young men who have sex with men.

2. This focus group will not be audio- or video-taped.

3. You can refuse to answer a question at any time. If you do not answer a question or want to end the interview, there will not be any penalty to you. No one except the study staff at [**Agency Name**] will be allowed to see the information you provide to us.

4. The interview is anonymous. Your name will not be attached to your responses.

5. You will receive $25.00 as a token of appreciation.

C. Risks

There are no physical risks to you by participating in this interview. No one will ask about your own behaviors, and you should not share this information during your interview.

D. Benefits

There are no direct benefits to you by being in this interview. The information you give us may help us have a better future study.

F. Token of Appreciation

You will receive $25 as a token of appreciation.

F. Persons to Contact

This study is run by: [*name of principal investigator and phone number*]. You may call [him/her] with any questions about being interviewed.

If you have questions about your rights as a participant or if you feel that you have been harmed, contact [*IRB committee or contact name and phone number*].

G. Confidentiality Statement

What you tell us is confidential. No one except the study staff at [**Agency Name**] and CDC will be allowed to see your comments, except as otherwise required by law. Those allowed to see your comments will not be able to tell that they are your comments because they will be given a summary of comments made by all the people we interview, without names included.

H. Right to Refuse or Withdraw

You may choose not to do this interview without penalty. You have the right to refuse to answer any questions. You can end the interview at any time you want.

I. Agreement

Do you have any questions?

Interviewer: Answer the participant's questions about the interview before proceeding to the next question.

You have read or had read to you the explanation of this study, you have been given a copy of this form, the opportunity to discuss any questions that you might have and the right to refuse participation. I am going to ask for your assent/consent to participate in this interview. By saying yes, you agree to participate in the interview. Do you agree to take part in the interview?

Date: _____ Interviewer initials in box confirm affirmative assent/consent

I have fully explained to the participant the nature and purpose of the procedures described above and the risks involved in its performance. I have asked if any questions have arisen regarding the procedures and have answered these questions to the best of my ability.

Date: _____ Signature of interviewer: _____

Focus Group Assent/Consent Form

English Version; Grade Reading Level by Flesch-Kincaid Method: 7.4

HIV Behavioral Surveillance for Young Men Who Have Sex with Men Focus Group Assent/Consent Form

A. Purpose

The [**Agency Name**] and the Centers for Disease Control and Prevention (CDC) are planning a survey of men between the ages of 13 and 17 who may be at risk for HIV infection and who will be asked to take an HIV test. The reason for the focus group is to learn about the best way to do this future study. We are asking you to be in the group because you may be able to give us with ideas about the future study.

B. Procedures

1. If you agree to be in the focus group, you will take part in a focus group with up to 10 other people that will last between 1 ½ and 2 hours.

2. During the session, people will be asked questions about the following issues:
   a. Ways to encourage young men to take the survey;
   b. Names of places young gay, bisexual, and/or other young men who have sex with men visit or social organizations they belong to;
   c. Reasons young men might not want to take an HIV test, and ways to encourage them to do so;
   d. The types of questions that would be important for us to ask so we can understand sexual behavior in gay, bisexual, and/or other young men who have sex with men.

3. This focus group will not be audio- or video-taped.

4. The focus group is anonymous. We will not record your name or any other characteristics that might identify you at any time during the interview. No one except the study staff at [**Agency Name**] will be allowed to see the information you provide to us.

5. You will be given $25.00 for being in the focus group.

6. You can refuse to answer a question at any time. If you do not answer a question or want to leave the focus group, there will not be any penalty to you.

C. Risks

There are no physical risks to you by participating in this focus group. No one will ask about your own behaviors, and you should not share this information during your session.

Other focus group members may say things that may make you feel uncomfortable. If this happens, the staff will help to resolve the problem.

D. Benefits

There are no direct benefits to you by being in this focus group. The information you give us may help us have a better future study.

G. Token of Appreciation

You will receive $25 as a token of appreciation.

F. Persons to Contact

This focus group is run by: [*name of principal investigator and phone number*]. You may call [him/her] with any questions about being in the focus group.

If you have questions about your rights as a participant or if you feel that you have been harmed, contact [*IRB committee or contact name and phone number*].

G. Confidentiality Statement

What you tell us is confidential. Your responses will be labeled with a study number only. No one except the study staff at [**Agency Name**] and CDC will be allowed to see the focus group's comments, *except as otherwise required by law.* Any comments made by persons in this group will not be attached to individual members but to the group as a whole.

H. Right to Refuse or Withdraw

You may choose not to do this interview without any penalty. You have the right to refuse to answer any questions. You can leave the focus group at any time.

I. Agreement

Do you have any questions?

Moderator: Answer the participant's questions about the focus group before proceeding to the next question.

You have read or had read to you the explanation of this study, you have been given a copy of this form, the opportunity to discuss any questions that you might have and the right to refuse participation. I am going to ask for your assent/consent to participate in this focus group. By saying yes, you agree to participate in the focus group. Do you agree to take part in the focus group?

Date: _____ Moderator initials in box confirm affirmative assent/consent

I have fully explained to the participant the nature and purpose of the procedures described above and the risks involved in its performance. I have asked if any questions have arisen regarding the procedures and have answered these questions to the best of my ability.

Date: _____ Signature of moderator: _____

Behavioral Assessment Assent Form

English Version; Grade Reading Level by Flesch-Kincaid Method: 7.7

[INSERT NAME OF LOCAL PROJECT]

The [**Agency Name**] and the Centers for Disease Control and Prevention (CDC) invite you to be part of a research study of young men that will look into how HIV is spreading and why young men's chances of getting infected with HIV are increasing. The information I will give you can help you decide if you want to join the study.

A. Why we are doing this project

The purpose of this study is to find out what we can learn about risk for HIV infection among young men. We will use this information to plan better programs to stop HIV from spreading among young men in your community. We will also use this information to decide if we should do studies like this one in other places. You can choose to be in this study or not.

B. What will happen

If you agree to be in this study, this is what will happen.

1. You will do a survey with a trained staff member.

The survey will take about 40 minutes and will ask you questions about:

- Yourself such as your background, education, health insurance, and your family
- Relationships with friends, family, and community
- Mental health
- Sexual life
- Alcohol and drug use
- HIV testing experiences
- Health conditions
- Experiences with violence and bullying
- Experience of being treated unfairly
- Information or help you may have received to protect yourself from getting infected with HIV

2. *[RDS only]* A staff member will explain how to tell up to 5 people you know about taking part in the study. You can decide if you want to tell people you know about the study; there is no penalty for deciding not to. You will receive $10 for each person who completes the survey because you told him about it.

3. If you agree to the survey, we will offer you a free HIV test. If you already know that you are HIV-infected, we would still like to offer you an HIV test today so that we can keep today's HIV test result together with your survey answers.

4. If you agree to an HIV test, we will ask you if we can store your blood sample for later testing This is an anonymous survey. We will not ask for your name or other identifying information. The survey has questions that are personal. They may be hard to talk about. You may refuse to answer any questions at any time for any reason. There is no penalty if you refuse to answer a question or you want to stop the survey.

If you agree to the HIV test, a counselor will talk to you for 10- to 15-minutes to explain how HIV spreads and how you can protect yourself and others from getting infected with HIV and other infectious diseases. The counselor will also tell you about HIV test results.

Standard Test [for grantees using the standard test]

For the test, we will [draw less than 1 tablespoon of your blood using a needle/swab the inside of your mouth for oral fluid] and test it for HIV. Your test results will be ready within one week. We will set up a day and time for you to get your results. A counselor will talk to you about what the test result means and we have experienced staff on hand that can help you see a doctor if you test positive for HIV as part of this study. [*For sites that allow HIV test phone results:* If you cannot come back for your HIV test results, you can talk to a counselor about your results by telephone.]

Rapid Test [for grantees using the rapid test]

You can get the result of your HIV test within 1 hour. We will [stick the tip of one of your fingers with a needle to obtain a few drops of blood/take a swab from your mouth]. A counselor will talk to you about what the test result means and we have experienced staff on hand that can help you see a doctor if you test positive for HIV as part of this study. If the test result is positive, or if you know you are already HIV- infected, we will [draw less than 1 tablespoon of your blood from your arm through a needle/stick the tip of one of your fingers to obtain a few drops of blood/swab the inside of your mouth for oral fluid] for a second test to be sure of the result. The result of the second test will be ready within one week. We will set up a day and time for you to get your results.

Rapid Test Algorithm (for grantees using the rapid test algorithm)

You can get the result of your HIV test within 1 hour. We will [stick the tip of one of your fingers to obtain a few drops of blood/take a swab from your mouth]. A counselor will talk to you about what the test result means and we have experienced staff on hand who can help you see a doctor if you test positive for HIV as part of this study. If the first test result is positive, or if you know you are already HIV- infected, we will do up to two additional HIV tests to check the result. For these tests, we will [draw less than 1 tablespoon of your blood from your arm through a needle/stick the tip of one of your fingers to obtain a few drops of blood/swab the inside of your mouth for oral fluid]. Finally, we will use this same [blood/oral fluid] to test your blood in the laboratory to be sure of the result. The result of the laboratory test will be ready within one week. We will set up a day and time for you to get your results.

Link between HIV Test Results and Survey

We will keep your HIV test results with your survey answers so we can learn about how activities that may increase the chance of getting infected with HIV are connected with HIV infection among young men in your community. Your name will not be on the test results or the survey. We will match your HIV test results with your survey answers by putting the same ID number on both. No one besides you will be told your HIV test results, and neither the survey answers nor the test results will be placed in any medical record.

Linkage to HIV Care

If you test positive for HIV, we will work with you to ensure that you are connected to a site of your choosing where you can receive free or low-cost confidential treatment. We have experienced staff on hand to help you see a doctor if you test positive for HIV as a part of this study.

Storage of Blood Sample

We would like to store any blood that is left over after we do your test. We plan to use this sample for studies we will do in the future. We will store your sample with some data about you, such as your age and race. We will not put your name on the sample and there will be no way to know it is yours: thus, we will not be able to report back any test results to you. We will not test for any genetic disease or use blood for cloning or commercial purposes. You can decline to let us store your blood and still be in this study. Your blood sample will be destroyed after this testing is completed.

C. <u>Things to consider</u>

There are minimal risks from being in this study:

1. You might feel that some of the questions are personal or embarrassing. All answers you give will be kept private. If there are questions you do not want to answer, you do not have to do so.

2. [*If using standard test and for finger stick]:* Drawing blood may cause temporary discomfort from the needle stick, bruising, bleeding, light-headedness, and local infection.

3. You may feel uncomfortable finding out you might have been infected with HIV. You can talk about your concerns with the counselor who tells you your HIV test results, if you wish.

4. If your HIV test result is negative, there is a slight chance that the results are wrong and that you could still be infected or test positive at some time in the future.

D. Benefits

Benefits you may get from being in this study include:

1. You will receive some condoms and information on HIV/AIDS and STDs.

2. You will, if you wish, get help to use medical services, mental health counseling, and health projects, as needed.

3. If your HIV test results are positive, a counselor will explain how you can protect others from getting infected with HIV. An experienced staff member will help you see a doctor.

4. If your test results are negative, a counselor will explain how you can protect yourself from getting infected with HIV and from other infections spread by sex.

Also, information from this study will help the **[Agency Name]** to know more about HIV and how it spreads. This information will be used to improve health programs and to develop new ways of protecting others from infection and promoting good health.

E. Alternatives

If you choose not to take part in the study but would like to take an HIV test, we will tell you where you can get an HIV test. You will get no medical treatment in this study.

F. Token of Appreciation

For completion of the survey, you will get $25. If you take part in the HIV test, you will get an additional $25. [*RDS only*] You will also receive $10 for each person who completes the survey because you told him about it.

G. Persons to Contact

This study is run by: [*name of principal investigator and phone number*]. You may call [him/her] with any questions about being in the study.

If you have questions about your rights as a participant or if you feel that you have been harmed, contact [*IRB committee or contact name and phone number*].
If you want one, you will get a copy of this form to keep.

H. Confidentiality Statement

What you tell us will be kept private. Your answers to the survey will be labeled with a study ID only. No one except the study staff at [**Agency Name**] and CDC will be allowed to look at the answers to the survey, *except as otherwise required by law*. Your answers will be grouped with survey answers from other persons.

If you know me, you may ask for another staff member so that your answers will be fully private.

I. Costs

You will not be charged for counseling, the HIV test, safer sex and HIV prevention materials, help with getting medical care or other services from other agencies or any other services provided by this study.

J. Right to Refuse or Withdraw

You can decide whether or not to take part in the study. You are not giving up any legal claims or rights for being a part of this study. If you agree to participate, you are free to quit at any time. You can choose to do the survey without having an HIV test.

K. Agreement

Do you have any questions?

Interviewer: Answer the participant's questions before proceeding to the next question.

You have read or had read to you the explanation of this study, you have been given a copy of this form if you want one, the opportunity to discuss any questions that you might have and the right to refuse participation. I am going to ask for your agreement to participate in this study. *(Assent will be documented by the interviewer in the computer as follows:)*

Do you agree to take part in the survey?

- ☐ Yes
- ☐ No

Do you agree to HIV counseling and testing?

- ☐ Yes
- ☐ No

Do you agree to storing a blood sample for future testing?

- ☐ Yes
- ☐ No

If survey declined:

We're interested in knowing why people do not want to do this study. Would you mind telling me which of the following best describes the reason you do not want to do this study?

You don't have time…..…….....	1
You don't want to talk about these topics……	2
Some other reason, or ……..…….....	3
You'd rather not say why…..…….……....	9