ATTACHMENT 5: ASSENT FOR ADOLESCENTS

For

Qualitative Evaluation of HIV Counseling, Testing, and Referral Services in Non-Health Care Settings: Eliciting Consumer Views

New OMB Application

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Attachment E: Assent for Adolescents

HIV Counseling, Testing and Referral (CTR) Services

Reading level 6.6 (assessed by Flesch-Kincaid)

Introduction and Purpose:
You have been asked to be in a focus group as part of a research study. The purpose of the study is to improve HIV testing services in non-medical settings so that more people can learn about their HIV status and get information and care. RTI International, a research company in North Carolina, is doing the study. The Centers for Disease Control and Prevention (CDC) is sponsoring the study.

Because you are here without a parent, we have an advisor here for you to talk to if you have questions. This advisor is someone who works at [NAME OF CBO] and is not a part of this study. You will have a chance to talk to this advisor in private before you decide if you want to join the study.

Procedures:
A focus group is when about 10 people get together to talk about a topic and share their opinions. During the group, the facilitator will invite you to share your opinions about HIV testing. We will also want to hear about your personal experiences in getting HIV tests. The focus group will take up to 2 hours.

We will be doing 21 focus groups in 4 cities. In total, about 250 people will be in the study.

A facilitator and up to 3 assistants will be there to guide the talk and take notes.

Risk/Discomforts:
There is no known physical risk to you from being in the study. You might feel embarrassed or upset by the things that are talked about in the focus group. If that happens, we will refer you to someone who can talk with you about your concerns. You can refuse to talk about any topic for any reason. You can stop being in the study at any time.

For this study, you have to reveal your HIV-status. Only people who have the same HIV status as you will be in your group. Someone you know could be in the group. We will ask everyone in the group to not talk about who is in the group or what is said. We can not be sure that this information will be kept private. We request that you do not tell anyone who is in the group or what you talk about today.

Benefits:
There is no direct benefit to you for being in this study. What we learn will help us to develop national HIV testing guidelines for non-medical settings. The information will help make HIV testing services better and more effective.

Confidentiality:
We will audio-tape the group discussion. Tapes will be kept in a locked cabinet. Notes will be made of the audiotapes. We will never refer to people by name in the notes, and you do not have to use your real name during the discussion. Staff will keep information about you as private as possible. There are limits to this privacy. For example, we will need to report some things to the proper authorities. These include:

- Child abuse
- Intentions to harm oneself or others
- Elder or dependent adult abuse

There will be up to two note takers and one observer sitting in the discussion room.

The notes from the focus group will be kept on a password-protected computer. Only authorized project staff will be able to see them. We will keep study forms that contain identifying information in a locked file cabinet accessible only to authorized staff. This includes the signed informed consent document. We will destroy everything three years after the study ends, except for your contact information, which will be destroyed two weeks after the focus group. Your name and other facts that might identify you will not appear when we present the study results. However, there is still a small risk that your privacy could be broken by another member of the focus group.

Reimbursement:
We will give you $50 cash to thank you for your time and effort. If 3 or fewer people come to the scheduled focus group, we will not conduct the FG. However, you will be given $15 for travel costs.

Right to Refuse or Withdraw:
It is your choice to be in this study. You can refuse to talk about any topic. You can leave the study at any time. If you decide not to be in this study or if you drop out, you can still be in other studies.

Persons to Contact:
If you have questions about the study, you can call Jennifer Uhrig at 1-800-334-8571 extension 3311. She can be reached between 9 AM and 5 PM Eastern Standard Time Monday – Friday. If you have questions about your rights as a research participant, you can call RTI's Office of Research Protection at 1-866-214-2043. I'm going to leave the room now for a few minutes to give you a chance to talk to [ADVISOR'S NAME] about this before we get started.

[INTERVIEWER MUST LEAVE ROOM WHILE YOUTH TALKS PRIVATELY WITH ADVISOR]

Before we go any further, do you have any questions you'd like to ask me?
May I ask you a few questions? **[See next page for questions]**

Your Consent:

I have read and understand this consent form (or it was read to me). I have talked about what it says with the host and the advisor. I had a chance to ask questions and my questions were answered. I was given a signed copy of this consent form. I agree to be in the study.

_____	_____	_____	_____
Participant's Signature	Date	Interviewer's Signature	Date

_____	_____
Advisor's Signature	Date

Comprehension Questions

Do you have to answer all of the questions that I ask you?	☐ Yes ☐ No
Will your name be connected to your answers?	☐ Yes ☐ No
Will we audio-tape the group?	☐ Yes ☐ No

NOTE: [If all answers correct, then CONTINUE with assent. If one (1) answer incorrect, reread the relevant portion of the written consent that answers the question and re-ask the question. If correct, CONTINUE with assent. Otherwise, TERMINATE. IF two (2) or more answers are incorrect, then TERMINATE.]