Appendix K1: Adolescent Assent Form

ASSENT FOR ADOLESCENTS, AGED 15 TO 17

Introduction and Purpose:

You have been asked to be in a small group interview as part of a research study. The purpose of the research study is to improve HIV care and treatment. RTI International, a research company in North Carolina is doing the study. The Health Resources and Services Administration, or HRSA, a federal health agency, is sponsoring this project.

Procedures:

We are organizing small groups of up to 4 people each to get together to talk about a topic and share their opinions. During the group, the facilitator will invite you to share your opinions about using text messages to help young people living with HIV stay healthy. We will also ask you to look at some text messages we have created and give us your opinions. The small group interviews will take up to 2 hours. A facilitator and one assistant will be there to guide the talk and take notes.

We will be doing 8 focus groups in North Carolina. In total, about 32 people will be in the study.

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 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 are also HIV positive 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 cannot be sure that this information will be kept private. We request that you do not tell anyone who is not in the group what you talk about today.

Benefits:

There is no direct benefit to you for being in this study. What we learn will help us develop text messages to send out to people with to encourage HIV care and treatment. The information will help people with HIV to live longer and healthier lives.

Confidentiality Respect for Your Privacy:

There will be one note taker sitting in the discussion room. We will also audio-record the group discussion. Audio files and notes will be saved to a password protected computer. We will never refer to people by name in the notes, and you do not have to use your real name during the discussion. Data will be kept private to the extent allowed by law. 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

We will keep study forms that contain identifying information in a locked file cabinet accessible only to authorized staff. We will move these forms to a locked storage building at the end of the study. We will destroy everything three years after the study ends except for your contact information, which will be destroyed two weeks after the 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 group.

Reimbursement:

We will give you \$50 cash to thank you for your time and effort. If only one person comes to the scheduled focus group, we will not conduct the group interview. However, you will be given \$25 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 23311. 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.

[RTI STAFF LEAVES 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:

Tour Consent.			
I have read this assent	t form (or it was read to	o me). I have talked about v	what it says with the
advisor. I had a chanc	e to ask questions and	my questions were answere	ed. I was given a copy of
this assent form. I agr	ee to be in the study (n	nark one): □ YES □ N	10
Advisor's Signature	Date	RTI Staff Signature	Date
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[DETACHED FROM ASSENT FORM. COPY FOR PERSON OBTAINING ASSENT ONLY]

Comprehension Questions

Do you have to answer all of the questions that I ask you?	□ Yes
that I ask you.	□ No
Will your name be connected to your answers?	□ Yes
unswers:	□ No
Will we audio-record the group?	□ Yes
	□ No

NOTE: [If all answers correct, then CONTINUE with assent. For incorrect responses, reread the relevant portion of the written consent that answers the question and re-ask the question. Also ask the participant to read it silently along with you. If correct, CONTINUE with assent. If still incorrect, ask the participant to show on the assent form where they are getting the incorrect answer from. Show the participant the correct language on the form and ask if he or she can say in their own words what the sentence means. If still incorrect, TERMINATE.

SCRIPT FOR INELIGIBLE PARTICIPANTS:

I'm sorry, but based on your responses to these questions, you are not eligible to participate in a small group interview at this time. However, we appreciate your willingness to join us today. As a token of appreciation, I can offer you \$25 to cover your travel costs today. Thank you.