

Generic Clearance
Formative Research and Tool Development

Attachment 9. Adult Consent

Public reporting burden of this collection of information is estimated to average 30 minutes per response including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0840)

Centers for Disease and Control Prevention

Consent to be in a Research Study

Thank you for your interest in this research study. Before you decide whether to agree to be in this study, please read this form along with me as I read it aloud and ask as many questions as you need to be sure you know what you will be asked to do.

Introduction: This study is being done by researchers from the Centers for Disease Control and Prevention (CDC).

What is the purpose of this study? The purpose of this study is to _____.

Why am I being asked to be in this study? We are asking you to be in this study because _____.

How long will you need me? The time commitment will depend on whether you are in the focus group, complete the survey, or do both. If you are asked to be in a focus group (a small meeting), we expect that it will last about 90 to 120 minutes. If you are asked to complete the survey, we expect that it will take you approximately 15 minutes.

What is going to happen during the study? As stated before, you will either participate in a focus group, complete a survey, or both. At the focus group, we will ask you to give your first name or a nick name to call you by. You will be asked to wear a name tag with your name or nickname on it. Some people who are working on the study will take notes during the focus group. Also, we plan to record what you say on audio tape. The tapes will help us learn more about what is said by all of you. For the survey, you will be asked to answer several questions about the motion comic.

What do you want me to do if I decide to be in this study? During the focus group, you will be asked to tell us about HIV/AIDS, STD, and the style and content of motion comics that would appeal to youth like you. If you are asked to complete a survey, we would like for you to respond to the questions in the survey.

Are there any risks to me if I decide to be in this study? There is low risk to you if you decide to be in this study. Since we may ask the group to discuss a lot of personal questions during the focus group, you may feel uneasy or have some concerns. You do not have to respond to any questions you do not want to either in the focus group or the survey.

Are there any benefits from being in this study? By being in this study you may be able to dispel myths about HIV/AIDS and STD. You may also influence the type of motion comic that is ultimately developed and help the community in the prevention of HIV/AIDS and STD.

Will the things I tell you be kept private? What you tell us will be kept private to the extent allowed by law. The things you tell us during the focus group and respond to in the survey will be kept secure by the research staff. We will safeguard your identity and information that you supply. That is, we will not tell anyone what you said and we will not tell anyone that you were part of a focus group or completed a survey about the study. However, if we think there may be child abuse or that you cause harm to yourself or others, we are required by law to report this concern to the proper authorities.

What is going to happen with the audio tapes of the focus groups? After the focus group, a person working on the study will listen to the audio tape and take notes on what was said by each person. On these notes, all names will be changed to “person 1”, “person 2,” “person 3” and so on. Only the people working on the study will be able to listen to the tapes. At the end of the study, we will erase the tapes and throw them away.

What will you do with the audio tapes of the focus groups and the responses to the surveys? The tapes, notes from the focus groups and responses to the surveys will be used to write papers on what we have found. We will share our findings with the people working on the study. These people will review the focus group reports and survey responses to help us understand what we have found. We also hope to make public our findings in a journal magazine, so that we can share what we found with other people. At no time, will anyone be able to know what you said or that you were in this study from anything that we write. We will also share our findings with you if you would like. You may also have a copy of any of the reports by getting in touch with us or giving us a number where we can call you.

Is there any cost if I take part in this study? The only cost to you for being in this study is your time for coming here today.

Is there any reimbursement if I take part in this study? There is no reimbursement for taking part in this study, although you will receive a token of appreciation of \$25, if you participate in the focus groups and an additional \$10 if you complete the survey.

Who should I call if I have questions about this study or think I may have gotten sick or been harmed by this study? If you have any questions about this study or your rights for being in this study, you may call Dr. Leigh Willis, 404-639-8447, or the CDC Institutional Review Board at 1- 800-584-8814.

Do I have to be in this study? You do not have to be in this study, it is up to you if you want to or not. You can stop being in this study at any time without any penalty or loss of benefits.

Do you have any further questions about this study?

Please print and sign your name below if you agree to be in this study and have your comments recorded during the focus group. By signing your name you also agree that you

have read this form and have had a chance to ask any questions you may have about the study. You will be given a copy of this consent form for you to take with you.

Print your Name _____ Date _____

Sign your Name _____ Date _____

Will you allow us to keep your contact information so we can provide you the results of the focus group? Circle yes or no.

Yes No (Please do not contact me again)

I observed the process of consent. The prospective participant read or was read this form, was given the chance to ask questions, appeared to accept the answers, and signed to enroll in the study.

Signature of Research Staff _____ *Date* _____