

Attachment C
Cognitive Interview Participant Informed Consent and Assent
Forms

Prescription Drug Redesign
Adult Cognitive Interview Participant Informed Consent Form
National Survey on Drug Use and Health (NSDUH)

Introduction

I am going to explain this study to you. You can stop me at any time if you have questions about anything I tell you.

The purpose of this study is to test some questions that will be used in the National Survey on Drug Use and Health, or NSDUH. The NSDUH is a large survey given to about 70,000 people across the country each year. It collects information on many health-related issues. The aim is to better serve all people throughout the United States. Right now, we're interested in testing some new questions on drug use that we might use in the NSDUH. The questions we are testing are about prescription drug use, use of alcohol and other drugs, and other health issues. We want to see how well people understand these questions and how they might go about answering them. RTI is carrying out this research study for the Substance Abuse and Mental Health Services Administration, or SAMHSA, which is part of the US Department of Health and Human Services. You are one of 40 participants at least 12 years old (including about 20 adults) who will review the new questions for this study.

Description of the Interview

Your participation in this interview will involve reading and answering questions on a laptop computer. The interview includes questions about the use tobacco, alcohol, drugs such as marijuana, and other health issues. For some questions I will ask you for information on how you came up with your answers to those questions. I may also ask you to put the questions in your own words. The interview will last approximately 90 minutes. Your participation in this study will end after you finish the interview.

Confidentiality/Your Rights

Taking part in the interview is completely voluntary. You can skip any interview questions you do not wish to answer. Your personal information will not be connected to your answers in any way. Federal law requires us to keep your answers confidential and to use these answers only for statistical purposes (the Confidential Information Protection and Statistical Efficiency Act of 2002). Interview data will be deleted from the laptop after the interview is over.

With your agreement, we will audio record your interview. You can ask us to pause or stop the recording at any time. Only RTI and SAMHSA research team members will be able to listen to the recordings. The recordings will be destroyed within 60 days of the end of this study. Comments from all interviews will be combined in a report that will not identify who made the comments.

[Read only if observer is present: A member of the RTI research team or representative(s) of SAMHSA is here with us today and would like to observe this interview from a separate observation room. If you do not want anyone else to observe your interview, we will simply ask this person (these people) to leave the observation room and then do the interview.]

Possible Risks and Benefits It is possible some of the survey questions may make you feel uncomfortable or upset. If this happens, I can tell you how to contact a counselor. You can ask me to stop the interview at any time. If you want to take a break at any time during the interview, please tell me.

There are no direct benefits to you from participating in this interview. However the answers you give will help us to improve the quality of questions for the NSDUH.

Payment for Participation

You will be given a Visa gift card worth \$40 for completing the interview.

Your Questions

If you have any other questions about the study, you can call Ms. Patty LeBaron at 1-800-334-8571 ext. 25204. If you have any questions about your rights as a study participant, you can call RTI's Office of Research Protection at 1-866-214-2043 (a toll-free number).

I will sign my name here to indicate that I have explained this information to you and that you have agreed to be interviewed.

Signature of Interviewer

Date

Read only if observer is present: I also will sign my name here to indicate that you have given your consent for a member of the RTI research team or representative of SAMHSA to observe the interview. [INTERVIEWER, PLEASE WRITE "NA" ON THE SIGNATURE LINE IF THE INTERVIEW IS NOT BEING OBSERVED.]

Signature of Interviewer

Date

Finally, I will sign my name here to indicate that you have agreed for the interview to be audio recorded.

Signature of Interviewer

Date

Participant Informed Assent (ADOLESCENT)

Introduction

I am going to explain this study to you. You can stop me at any time if you have questions about anything I tell you.

The purpose of this study is to test some questions that will be used in the National Survey on Drug Use and Health, or NSDUH. The NSDUH is a large survey given to about 70,000 people across the country each year. It collects information on many health-related issues, to better help everyone in the United States. We're interested in testing some questions that we might use in the study. We want to see how well people understand these questions. We also want to know how people go about answering the questions. RTI is doing this study for the Substance Abuse and Mental Health Services Administration, or SAMHSA. You are one of 20 participants between the ages of 12 to 17 who will help us test the new questions.

Description of the Interview

You will be reading questions on a laptop computer about health and substance use. The interview includes questions about use of tobacco, alcohol, drugs such as marijuana, and other questions about your health. Your participation in this interview is voluntary. You can stop the interview at any time.

Our interview today will last about an hour and a half. I will ask you some questions from the survey. Then I will ask you some more questions to get your thoughts about the questions. I may ask you to put some of the questions into your own words. We also would like to audio record what you say during the interview. Only the people who work on this study will hear the recording. It will help us make sure we have understood your answers. If you don't want us to audio record you, that's okay.

Confidentiality/Your Rights

You don't have to answer a question if you don't want to. If you want to take a break at any time, just tell me. Your name will be kept private. No one else will see your answers to these questions. Your parents will not find out about your answers to questions. Interview data will be deleted from the laptop after the interview is over. The only exceptions to this promise of confidentiality are if you tell me that you intend to seriously harm yourself or someone else or if you have been abused or if you identify an adult who has given you drugs; in these situations I may need to notify a mental health professional or other authorities.

Possible Risks and Benefits

Some of the the questions we ask may make you feel uncomfortable or upset. If this happens, let me know right away, and we can either take a break or I can give you information about talking with a counselor.

We are required by law to keep your answers private. The law also requires the study to use your answers only to learn how the questions work. The name of this law is the Confidential Information Protection and Statistical Efficiency Act of 2002.

There are no direct benefits to you from doing this interview. Your involvement in this study will help us improve the questions for the NSDUH.

When we finish, I will give you a \$30 Visa gift card to thank you for taking time to talk to me.

If you or your parent/guardian have any other questions about the study, you can call Ms. Patty LeBaron at 1-800-334-8571 ext. 25204. If you or your parent/guardian have any questions about your rights as a participant in this study, you can call RTI's Office of Research Protection at 1-866-214-2043.

I will sign my name here to indicate that I have explained this information to you and that you have agreed to be interviewed. You will be given a copy of this form.

Signature of Interviewer

Date

I will sign my name here to indicate that you have agreed for the interview to be audio recorded.

Signature of Interviewer

Date

Participant Assent to Be Observed (ADOLESCENT)

[Another person who works on the study/A person or people who work(s) with the sponsor of this study] also is here with us today. This person (These people) would like to watch your interview in a separate observation room. We have already talked with your parent or guardian about this, and they have said it is okay to have this person (these people) watch the interview. What you say will still be kept private. It's okay if you don't want this person (these people) to watch your interview. We will simply ask that person(them) to leave the observation room.

Is it OK for this person (them) to watch your interview?

CHECK ONE OF THE BOXES BELOW. SIGN AND DATE FORM

Other study team member or sponsor representative may observe the interview.

Other study team member or sponsor representative may not observe the interview.

Signature of Interviewer

Date