

Attachment E
Cognitive Interview Participant Informed Consent Forms
December 3, 2010

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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 28 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.¹ The interview includes questions about the use of prescription pain relievers and stimulants, tobacco, alcohol, drugs such as marijuana, and other health issues. For some questions the interviewer will ask you for information on how you came up with your answers to those questions. The interviewer may also ask you to put the questions in your own words. The interview will last approximately 60 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. The interview will be done in private. Your personal information will not be connected to your answers in any way. Federal law requires us to keep your responses private.² 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. If you decide to stop the interview, that won't affect any services you are entitled to receive.

[Read only if observer is present: A member of the RTI research team or representative 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 to leave the observation room and then do the interview.]

Possible Risks and Benefits

¹ In the third round of cognitive interviews, the following sentence will be added: "You also can listen to an audio recording of the questions"

²The information you provide will be used for statistical purposes only. In accordance with the Confidential Information Protection provisions of Title V, Subtitle A, Public Law 107-347 and other applicable Federal laws, your responses will be kept confidential and will not be disclosed in identifiable form to anyone other than employees or agents. By law, every employee of the Center for Behavioral Health Statistics and Quality (CBHSQ), SAMHSA as well as every agent has taken an oath and is subject to a jail term of up to 5 years, a fine of up to \$250,000, or both if he or she willfully discloses any identifiable information about you.

It is possible some of the survey questions may make you feel uncomfortable or upset. You can tell the interviewer if you do not want to answer any questions. You also can ask the interviewer to stop the interview at any time. If you want to take a break at any time during the interview, please tell the interviewer. If you find the survey questions to be upsetting for any reason, the interviewer can tell you how to contact a counselor. There is a very small chance that someone might find out what you tell us during the interview. 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 2002.³

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 Mr. Larry Kroutil at 1-800-334-8571 ext. 26067. Or, you can call Ms. Liz Dean at 1-800-334-8571 ext. 27445. 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. You will be given a copy of this form.

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 an member of the RTI research team or representative of SAMHSA to observe the interview. If I haven't signed my name here, that means you didn't want the observer to stay. [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. If I haven't signed my name here, that means you didn't want the interview to be audio recorded.

Signature of Interviewer

Date

³The information you provide will be used for statistical purposes only. In accordance with the Confidential Information Protection provisions of Title V, Subtitle A, Public Law 107-347 and other applicable Federal laws, your responses will be kept confidential and will not be disclosed in identifiable form to anyone other than employees or agents. By law, every employee of the Center for Behavioral Health Statistics and Quality (CBHSQ), SAMHSA as well as every agent has taken an oath and is subject to a jail term of up to 5 years, a fine of up to \$250,000, or both if he or she willfully discloses any identifiable information about you.

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 12 participants between the ages of 12 to 17 who will help us test the new questions. You were chosen to participate because you told us you were interested.

Description of the Interview

You will be reading questions on a laptop computer about ways that some people use different drugs. Some of these drugs are called pain relievers and other drugs are called stimulants. Doctors write prescriptions for these drugs. 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 1 hour. 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. The interview will be done in private. Your name also will be kept private. Your responses will be kept private under federal law.⁴

Possible Risks and Benefits

Some of the the questions we ask may make you feel uncomfortable or upset. You can tell me if you do not want to answer any questions. If you should feel uncomfortable or upset during the interview, you may ask the interviewer to take a break or skip any of the questions. You also can stop the interview whenever you want. If you find the questions to be upsetting for any reason, let me know right away, and I will give you information about talking with a counselor. [IF PARENT/GUARDIAN ACCOMPANYING ADOLESCENT, ADD: I also will give your parent or guardian this same information.]

There also is a very small chance that someone might find out what you tell us during the interview. 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 2002.¹

⁴The information you provide will be used for statistical purposes only. In accordance with the Confidential Information Protection provisions of Title V, Subtitle A, Public Law 107-347 and other applicable Federal laws, your responses will be kept confidential and will not be disclosed in identifiable form to anyone other than employees or agents. By law, every employee of the Center for Behavioral Health Statistics and Quality (CBHSQ), SAMHSA as well as every agent has taken an oath and is subject to a jail term of up to 5 years, a fine of up to \$250,000, or both if he or she willfully discloses any identifiable information about you.

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.

I will give you a copy of this form to keep. 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 Mr. Larry Kroutil at 1-800-334-8571 ext. 26067. Or, you can call Ms. Liz Dean at 1-800-334-8571 ext. 27445. 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. It won't cost anything to call these numbers.

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. If I haven't signed my name here, that means you didn't want 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 who works with the sponsor of this study] also is here with us today. This person 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 watch the interview. What you say will still be kept private. It's okay if you don't want this person to watch your interview. We will simply ask that person to leave the observation room.

Is it OK for this person 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