

Attachment F

2013 Intro and Informed Consent

INTRODUCTION AND INFORMED CONSENT FOR INTERVIEW RESPONDENTS AGE 18+

IF INTERVIEW RESPONDENT IS NOT SCREENING RESPONDENT,
INTRODUCE YOURSELF AND STUDY AS NECESSARY: Hello, I'm _____,
and I'm working on a nationwide study sponsored by the U.S. Public Health
Service. You should have received a letter about this study. (SHOW LEAD
LETTER, IF NECESSARY.)

READ THE BOXED INFORMATION BELOW BEFORE STARTING EVERY INTERVIEW

This year, we are interviewing about 70,000 people across the nation. You have been randomly chosen to take part. You will represent over 4,500 other people who are similar to you. You may choose not to take part in this study, but no one else can take your place. We will give you \$30 when you finish the interview.

GIVE STUDY DESCRIPTION TO R IF YOU HAVE NOT ALREADY DONE SO.

This study asks about tobacco, alcohol, and drug use or non-use, knowledge and attitudes about drugs, mental health, and other health issues. It takes about an hour. You will answer most of the questions on the computer, so I will not see your answers. We are only interested in the combined responses from all 70,000 people, not just one person's answers. This is why we do not ask for your name and we keep your answers separate from your address. RTI may contact you by phone or mail to ask a few questions about the quality of my work. This is why we ask for your phone number and mailing address at the end of the interview.

While the interview has some personal questions, federal law keeps your answers private. We hope that protecting your privacy will help you to give accurate answers. You can quit the interview at any time and you can refuse to answer any questions.

If it is all right with you, let's get started.

(Can we find a private place to complete the interview?)

INTRODUCTION AND INFORMED CONSENT FOR INTERVIEW RESPONDENTS AGE 12-17

**FIRST, READ THE PARENTAL PERMISSION SCRIPT BELOW AND
OBTAIN PERMISSION FROM THE PARENT**

Your (AGE) year-old child has been selected to be in this study. Your child's participation is voluntary. This interview asks about tobacco, alcohol, and drug use or non-use, knowledge and attitudes about drugs, mental health, and other health related issues. All of your child's answers will be confidential and used only for statistical purposes. Since your child will answer most of the questions on the computer, I will never see the answers, and you are not allowed to see them either. If it is all right with you, we'll get started.

(Can we find a private place to complete the interview?)

**THEN, READ THE BOXED INFORMATION BELOW BEFORE STARTING EVERY
INTERVIEW WITH A 12-17 YEAR OLD**

This year, we are interviewing about 70,000 people across the nation. You have been randomly chosen to take part. You will represent over 1,000 young people in this country who are similar to you. You may choose not to take part in this study, but no one else can take your place. We will give you \$30 when you finish the interview.

GIVE STUDY DESCRIPTION TO R IF YOU HAVE NOT ALREADY DONE SO.

This study asks about tobacco, alcohol, and drug use or non-use, knowledge and attitudes about drugs, mental health, and other health issues. It takes about an hour. You will answer most of the questions on the computer, so I will not see your answers. Your answers will never be seen by either your parents or your school. We are only interested in the combined responses from all 70,000 people, not just one person's answers. This is why we do not ask for your name and we keep your answers separate from your address. RTI may contact you by phone or mail to ask a few questions about the quality of my work. This is why we ask for your phone number and mailing address at the end of the interview.

While the interview has some personal questions, federal law keeps your answers private. We hope that protecting your privacy will help you to give accurate answers. You can quit the interview at any time and you can refuse to answer any questions.

If it is all right with you, let's get started.

Attachment G
2013 Study Description



**U.S. Public Health Service
Center for Behavioral Health
Statistics and Quality**

Study Description

Your address is one of several in this area randomly chosen for the 2013 National Survey on Drug Use and Health. This study, sponsored by the United States Public Health Service, collects information for research and program planning by asking about:

- tobacco, alcohol, and drug use or non-use,
- knowledge and attitudes about drugs,
- mental health, and
- other health issues.

You cannot be identified through any information you give us. Your name and address will never be connected to your answers. Also, federal law requires us to keep all of your answers confidential. Any data that you provide will only be used by authorized personnel for statistical purposes according to the Confidential Information Protection and Statistical Efficiency Act of 2002.

The screening questions take just a few minutes. If anyone is chosen, the interview will take about an hour. You can refuse to answer any questions, and you can quit at any time. **Each person who is chosen and completes the interview will receive \$30 in cash.**

If you have questions about the study, call the Project Representative at 1-800-848-4079. If you have questions about your rights as a study participant, call RTI's Office of Research Protection at 1-866-214-2043 (a toll-free number). You can also visit our project website: <http://nsduhweb.rti.org/> for more information.

Thank you for your cooperation and time.

Michael Jones, Project Officer
Center for Behavioral Health Statistics and Quality
Substance Abuse and Mental Health Services Administration (SAMHSA)
U.S. Public Health Service
Department of Health and Human Services

Your confidentiality is protected by the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA, PL 107-347). Any project staff or authorized data user who violates CIPSEA may be subject to a jail term of up to 5 years, a fine of up to \$250,000, or both.

Attachment R

2013 NSDUH Confidentiality Agreement

This agreement is intended for review and signature by employees of RTI International and all its subcontractors who have access to information designated as confidential on a research study sponsored by SAMHSA/CBHSQ covered under CIPSEA. This agreement must be renewed each year as part of mandated CIPSEA training to maintain access to confidential project information.

Assurances of Confidentiality under CIPSEA

For any research study sponsored by the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Behavioral Health Statistics and Quality (CBHSQ) that is covered under the **Confidential Information Protection and Statistical Efficiency Act (CIPSEA) of 2002*** and Section 501(n) of the Public Health Service Act, all data and associated materials collected and/or utilized on that study are subject to protection by CIPSEA. CIPSEA ensures the confidentiality of all information provided is protected by Federal Law and stipulates that all information collected shall be used exclusively for statistical purposes. All research subjects contacted on SAMHSA/CBHSQ's behalf by RTI International are notified of these protections prior to study participation.

You have been identified as a person who has access to confidential information on a SAMHSA/CBHSQ-sponsored study covered under CIPSEA (NSDUH and/or DAWN**) and therefore have been designated as an **Agent under CIPSEA**. This confidential information includes (but is not limited to) all electronic and hard copy documents containing respondent information and data, as well as non-data related records containing information that could identify a location or respondent associated with a particular study.

Protection Agreement under CIPSEA

Per CIPSEA regulations, you agree that any materials that would permit the identification of research subjects are to be treated as confidential, and that you will never share or use that confidential information with anyone else or in a manner other than those authorized by CBHSQ. This includes never disclosing confidential information with law enforcement officials, officers of the court or your supervisor (if not also authorized as an Agent).

To ensure the protection of all confidential information in both physical and electronic form, as an Agent, you also agree to:

- 1) keep all confidential information in a space where access is limited only to authorized personnel, whether on a computer or in hard copy form;
- 2) keep all confidential information within computer memory controlled by password protection;
- 3) maintain a secure location (such as file cabinet or locked drawer) for printed materials, diskettes, and data on hard disks of personal computers when not in use;
- 4) never remove confidential information from your approved worksite without prior approval from CBHSQ and/or RTI International;
- 5) never permit any unauthorized removal of any confidential project information from the limited access space protected under the provisions of this agreement without first notifying and obtaining written approval from RTI;
- 6) notify RTI when you no longer have access to electronic or hard copy files or printed materials containing confidential project information;

* Public Law 107-347, Title V; for more info: http://www.whitehouse.gov/omb/fedreg/2007/061507_cipsea_guidance.pdf

**National Survey on Drug Use and Health (NSDUH); Drug Abuse Warning Network (DAWN)

- 7) when appropriate, return all confidential project information to RTI;
- 8) complete annual training on restrictions associated with the use of confidential information;
- 9) agree that representatives of CBHSQ have the right to make unannounced and unscheduled inspections of the facilities where you work to evaluate compliance with this agreement;
- 10) notify RTI International immediately upon receipt of any legal, investigatory, or other demand for disclosure of confidential project information;
- 11) notify RTI International immediately upon discovering any breach or suspected breach of security or any disclosure of confidential project information to unauthorized parties or agencies.
- 12) and agree that obligations under this agreement will survive the termination of any assignment with SAMHSA/CBHSQ and/or RTI International.

Penalties under CIPSEA

Any violation of the terms and conditions of this agreement may subject you, the Agent, to immediate termination of access to confidential information by RTI International or CBHSQ, and will require the immediate return of all electronic and hard copy files and materials in your possession.

Any violation of this agreement may also be a violation of Federal criminal law under Title V, subtitle A of the E-Government Act of 2002 (P.L. 107-347); and/or Section 501(n) of the Public Health Services Act. Alleged violations under the Title V, subtitle A of the E-Government Act of 2002 are subject to prosecution by the United States Attorney. The penalty for violation of subtitle A of the E-Government Act of 2002 is a **fine of not more than \$250,000 and imprisonment for a period of not more than 5 years**. In addition to the above, all relevant statutory and regulatory penalties apply.

Your signature (whether in electronic or written form) below affirms your understanding and acknowledgement of all the regulations, requirements and penalties associated with CIPSEA as part of your work on this SAMHSA/CBHSQ project for RTI International.

Name

ID Number (if applicable, RTI employees only)

Signature

Company Name

Date

Job Title