

Attachment 1: Confidentiality pledges to be cognitively tested

The Public Health Service Act provides us with the authority to do this research (42 United States Code 242k). All information which would permit identification of any individual, a practice, or an establishment will be held confidential, will be used for statistical purposes only by NCHS staff, contractors, and agents only when required and with necessary controls, and will not be disclosed or released to other persons without the consent of the individual or the establishment in accordance with section 308(d) of the Public Health Service Act (42 USC 242m) and the Confidential Information Protection and Statistical Efficiency Act (PL-107-347).

Public reporting burden for this collection of information is estimated to average 60 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 Information Collection Review Office; 1600 Clifton Road NE, MS D-74, Atlanta, GA 30333, ATTN: PRA (0920-0222).

Form Approved OMB #0920-0222; Expiration Date: 07/31/2018

Note to reviewers: The confidentiality pledges will be tested in the context of our generic/non-project specific CQDER informed consent document. However, probing will focus on the language of the three confidentiality pledges. See footnote #1 at bottom of consent form.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Road
Hyattsville, Maryland 20782

Generic/Non-project Specific Informed Consent Form for One-on-one Interviews

You are being asked to take part in a research study. This consent form tells you about the study and what you will be asked to do. You can choose to take part in the study or not. If you choose to take part, you will need to sign this form.

Purpose of the Research

Surveys are used to collect information on the health and wellbeing of Americans. The surveys help to develop programs to improve the health and health care of people living in the United States.

Before health surveys are conducted, the questions are tested with people of different backgrounds. It is important that the questions make sense, are easy to answer, and that everyone understands the questions the same way. The National Center for Health Statistics conducts these tests for the surveys it sponsors and for other survey programs. If you agree to take part in this test, we will ask you to answer the survey questions. Then, we will ask you to explain what you were thinking and how you came up with your answers.

The questions that we are working on today are about [fill].

Your interview will show us how to improve these questions. In the future, we may also study your interview along with interviews from other projects. This type of study will teach us about the different kinds of problems people have answering survey questions. The study will help us write better questions in the future.

Procedures

An interviewer will ask you some survey questions. Then, the interviewer will ask you to explain what you were thinking as you answered the questions. The interviewer will ask you if there were any words that were confusing and if you understood what was being asked.

The interview will last no more than 60 minutes, and we will give you \$40. You will also be asked to fill out a personal information sheet.

You may find that some of the questions we are testing are sensitive. You may choose not to answer any question for any reason. If you do not want to answer a question, say so, and we will move on to the next one. You may also stop the interview at any time. While the interview is going on, researchers from the Center for Questionnaire Design and Evaluation Research (CQDER), who are working on the project may watch the interview.

If you have questions about how the project works, contact Ms. Karen Whitaker by phone at (301) 458-4569, or by mail at NCHS, Room 6330, 3311 Toledo Rd., Hyattsville, MD 20782.

Recordings

We would like to video record your interview. The recording allows us to more carefully study and improve the questions. At the bottom of this form, you will be asked if you are willing to have the interview recorded. If you agree, you may still ask to stop the recording at any time, and we will turn off the machine. If you decide to stop recording, we will ask your consent to retain the portion already recorded. When the interview is finished, you may watch the recording.

If you agree to record the interview, we will keep it in a locked room either in a secure storage cabinet or on a password-secured computer that is not connected to the internet. When in use all recordings will be in the safe keeping of a staff person from the Center for Questionnaire Design and Evaluation Research (CQDER).

At the end of the interview, we may ask you for special permission to play the recording in a more public setting. For example, the interview could be played at a conference or for students who want to learn how to write survey questions. If you do not agree to this special permission, we will not allow anyone other than staff working directly on this project to watch the recording.

Privacy

We are required by law¹ to tell you what we will do with the recording. We must also tell you how we will protect your privacy.

Audio and video recordings are stored in a locked room or secured by a password. All recordings are labeled by a code number, date, time, and project title. The recording is never labeled with your name or other personal facts.

Materials with personal facts (such as names or addresses) are also stored in a locked room. Only CQDER staff has access to this material.

Your name or other personal facts that would identify you will not be used when we discuss or write about this study. People working on this project, however, may recognize you or your voice.

If you have questions about NCHS privacy laws and practices, contact Eve Powell-Griner, Ph.D., Confidentiality Officer at 1-888-642-4159.

Benefits and Risks

There are no direct benefits from taking part in this study.

The possible risks of taking part in this study are minimal. We will take all possible steps to protect your privacy. You do not have to give us any information that you do not want to, and you can choose not to answer any question in the interview. You may also stop at any time and still receive the full \$40.

If you have any questions about this study, please call the office of the Research Ethics Review Board at the National Center for Health Statistics, toll-free at 1-800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol #2010-19-XX. Your call will be returned as soon as possible.

Please Read and Sign Below if You Agree

- I freely choose to take part in this research study.

I allow NCHS to video record my interview. I also allow NCHS to play my video recording to other people working on this project either in the CQDER or in another location under the direct supervision of CQDER staff.

- Yes • No

IF YES:

I allow NCHS to retain my video recording for future research on how people react to survey questions and how survey questions can be hard to understand or hard to answer.

- Yes • No

Respondent Signature

Print name

Date

¹Confidentiality pledges to be evaluated:

Option 1

All information that relates to or describes identifiable characteristics of individuals, a practice, or an establishment will be used only for statistical purposes. NCHS staff, contractors and agents will not disclose or release responses in identifiable form without the consent of the individual or establishment in accordance with section 308(d) of the Public Health Service Act (42 USC 242m) and the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA ,Title 5 of Public Law 107-347). In accordance with CIPSEA every NCHS employee, contractor and agent have taken an oath and is subject to a jail term of up to five years, a fine of up to \$250,000, or both if he or she willfully discloses ANY identifiable information about you. Electronic transmission of your information will be monitored in accordance with the Cybersecurity Enhancement Act of 2015.

Option 2

NCHS, its employees and agents, will use the information you provide for statistical purposes only and will hold the information in confidence to the fullest extent permitted by law¹. In accordance with section 308(d) of the Public Health Service Act (42 USC 242m) and the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA, Title 5 of Public Law 107-347), NCHS staff, contractors and agents will not disclose or release responses in identifiable form without the consent of the individual or establishment. In accordance with CIPSEA, every NCHS employee, contractor and

¹ The Cybersecurity Enhancement Act of 2015 permits information sent to federal agencies to be reviewed in the event of a suspected cybersecurity threat. This review may disclosure personally identifiable information.

agent have taken an oath and is subject to a jail term of up to five years, a fine of up to \$250,000, or both if he or she willfully discloses ANY identifiable information about you.

Option 3 All information which would permit identification of an individual, a practice, or an establishment will be used by NCHS staff, contractors, and other agents authorized by NCHS only to perform statistical activities. Except to comply with the Cybersecurity Enhancement Act of 2015 which permits information sent to federal agencies to be reviewed in the event of a suspected cybersecurity threat, the information will be held confidential, and will not be disclosed or released to other persons without the consent of the individual or establishment in accordance with section 308(d) of the Public Health Service Act (42 USC 242m) and the Confidential Information Protection and Statistical Efficiency Act (PL-107-347) which also requires that every employee as well as every agent has taken an oath and is subject to a jail term of up to five years, a fine of up to \$250,000, or both if he or she willfully discloses ANY identifiable information about you.