

Appendix 4 – Adult Informed Consent



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

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 your health behavior and experiences before and during your pregnancy and early infancy of your child including family history of health conditions, genetic counseling for cancer risk, prescription and non-prescription drugs, and environmental exposures.

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 to fill out the questionnaire. Then, the interviewer will ask you to explain what you were thinking as you answered the questions. Then 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 90 minutes, and we will give you \$50. 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) and the Centers for Disease Control and Prevention, who are working on the project may listen to 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 audio 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 listen to 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).

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 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 other 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 \$50.

Conducting an interview at a mutual location²

In order for you to take part in the study today, we agreed to meet at this location. Meeting at this location is your choice. However, you are urged to choose a place that is private so that you will feel comfortable answering the questions. We will protect any materials that contain your personal information and transport them to the Centers for Disease Control and Prevention's National Center for Health Statistics.

If you have any questions about this study, please call the office of the 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 [Note: The amendment number will be inserted into the form once NCHS ERB approval has been received]. 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 audio record my interview. I also allow NCHS to play my audio 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 audio 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

Participant Signature

Print name

Date

¹The 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).

²This paragraph will be included in the consent form for those interviews conducted offsite.