Attachment 4 – Informed consent for cognitive interviews

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

The purpose of the National Electronic Health Records Survey is to collect information about physicians' use of electronic health records in their practices.

The Questionnaire Design Research Laboratory at the National Center for Health Statistics is conducting a study to evaluate the National Electronic Health Records Survey. It is important that the questions make sense, are easy to answer, and that everyone understands the questions the same way so that appropriate data collection mechanisms can be constructed.

Your interview will help us improve the National Electronic Health Records Survey. 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 in answering survey questions and filling-out data collection forms. This study will help us write better questions and design better data collections forms in the future.

Procedures

An interviewer will ask you about your experiences filling out the National Electronic Health Records Survey. The interviewer will also ask you about your opinions of the form.

The interview will last no more than 60 minutes, and we will give you $100. You will be asked to fill out a personal information sheet.

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.

If you have questions about how the project works, contact Ms. Karen Whitaker by phone at (301) 458-4569, or by mail at Centers for Disease Control and Prevention's National Center for Health Statistics, Room 3215, 3311Toledo Rd., Hyattsville, MD 20782.

Recordings

We would like to audio record your interview. The recording allows us to keep a record of what was asked and what was said. At the bottom of this form, you will be asked if you are willing to have the interview recorded. If you agree, you may 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 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 Questionnaire Design Research Laboratory (QDRL).

At a later time, staff from the Centers for Disease Control and Prevention's National Center for Health Statistics who work with the National Electronic Health Records Survey may listen to the interview. However, they must agree to keep your personal data private. Also, they must listen to the interview in the QDRL or with QDRL staff present.

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 conduct these types of interviews. If you do not agree to this special permission, we will not allow anyone other than staff working directly on this project to listen to the recording.

Privacy

We are required by law[1] 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 QDRL staff have 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 your voice.

Your individual responses will not be shared with other physicians. Only summary reports will be available to those interested in the results of the National Electronic Health Records Survey study.

If you have questions about the Centers for Disease Control and Prevention's National Center for Health Statistics privacy laws and practices, contact Eve Powell-Griner, Confidentiality Officer at 1-888-642-4159.

Benefits and Risks

Other than the $100 you receive, 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 $100.

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 Centers for Disease Control and Prevention's 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 in to 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 QDRL or in another location under the direct supervision of QDRL 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

_____ _____ _____

Respondent Signature **Print name** **Date**

[1]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).
