Attachment G - CCQDER Data Storage and Access Policy

Background

Cognitive Interviewing Methodology is a question evaluation method that examines the way in which survey questions perform. It offers a detailed depiction of the meanings and processes used by respondents to answer survey questions. This method provides insight into data quality as it is able to examine question validity and item response error. Within the Federal statistical system, cognitive interviewing methodology is a commonly used method for developing and evaluating survey questions. The Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) at the National Center for Health Statistics (NCHS) conducts numerous cognitive interview studies for sponsors both within and outside of the center.

In keeping with standard practice for cognitive interview studies, cognitive interviews (as well as focus group discussions) conducted by the CCQDER are video and/or audio recorded. These recordings serve as the raw data that lead to the analytical findings of each project. Importantly, recordings allow for an evidence-based approach for question evaluation and design. While both video and audio recordings are valuable as raw data, video is the richest format for data as it includes both verbal and nonverbal reactions to interviewer questions. While audio is limited to pure verbal interactions, video provides additional means to understand any confusion or to explore reactions otherwise missed through audio alone.

After the recordings are used for analytical purposes, they retain their qualitative value in three particular areas. Recordings: 1) foster transparency by providing evidence of analytic findings; 2) allow for the sharing of the methodological process with data users; and 3) may provide data for future question design research without additional burden to the public. Ideally, recordings of interviews should be maintained in their original format for as long as they retain this qualitative value.

However, the benefits of retaining recordings must be balanced with the risk of disclosure that exits as long as recordings of interviews are kept. The likelihood and implications of disclosure vary depending on media format as well as the type of respondent and interview topic. For example, video recordings are susceptible to identification of respondents through either facial or voice recognition, while audio recordings are vulnerable only through voice recognition. Additionally, disclosure of some topics and types of respondents may have more serious consequences for respondents. Therefore, interviews conducted with youth or those that cover topics of illegal behavior, for example, may merit added steps to minimize risk of disclosure. Thus, when assessing risk and determining data storage requirements, it is necessary to consider a variety of factors at the project and/or interview level.

In regards to the storage of interview recordings, The Office of Management and Budget stipulates in Guideline A.5.1 of the statistical policy directive, Standards and Guidelines for Cognitive Interviews:

A plan is prepared to store the raw data according to an agencies' record management schedule. If not available, a schedule for storing raw data for specified length of time based on the nature of the data and project should be developed. Each agency has the legal responsibility to safeguard respondent identity and personally identifiable information, and should treat all data according to their stated security and confidentiality procedures.

This document delineates the NCHS plan for housing the raw data from its question evaluation studies in order to minimize risk of disclosure. In doing so, the policy specifies the procedures for both the storage of and access to CCQDER recordings of interview and focus group discussions. Storage and access pertain to 1) the permitted retention time for interviews, 2) the required media format for storage, and 3) the persons permitted access.

Terms and Definitions

CCQDER, the Collaborating Center for Question Design and Evaluation Research, refers to the NCHS question evaluation research program.

QDRL, the Question Design Research Laboratory, refers to the secured facility housing the infrastructure that supports the collection, processing and maintenance of question evaluation data. CCQDER manages the QDRL with the support of contracted staff, or non-Federal employees. QDRL contract staff are permitted access to QDRL data within the confines of the QDRL.

CCQDER Interviews are those interviews conducted and recorded by CCQDER staff as well as those conducted by non-federal employees contracted by CCQDER. Contracted interviewers have access to only their recorded interviews until turning them over to CCQDER (should they be conducted outside the QDRL).

Policy Objectives

The objectives of the CCQDER data storage and retention policy are:

- To maintain recordings in the optimal useable format for as long as the interview continues to hold relevance and has qualitative value for likely use in federal question evaluation research projects or activities.
- To identify interviews that have confidentiality risks based on elevated privacy concerns.
- To minimize confidentiality concerns by specifying rules for which persons are permitted access to interview recordings.
- To minimize confidentiality concerns by stipulating the terms of regular review and disposal of each interview recording stored within the QDRL.

Factors for Determination of Retention Status

An interview's retention status pertains to 1) retention time: how long a recorded interview will be stored, 2) media format: the media format used to store a recorded interview, and 3) authorized viewers: the persons permitted access a recorded interview. An interview's Retention Status is determined by several project and interview-level factors. Thus, each interview has its own individual retention status independent of the other interviews within the same project. An interview's retention status is based on the type of consent/assent agreed upon by the respondent and whether the interview is considered to be a restricted interview based on the type of respondent or the interview topic. The retention status matrix (presented in the table below) describes all possible retention status levels and stipulates the retention time, media format, and permitted access for each retention status category. (See Attachments A, C and D, revised informed consent and special consent forms. The child assent form is not attached because it is individual to each project. Note: attachment labels A, C and D correspond to their designations in the original package.)

1. Type of Consent

Basic informed consent: In order to participate in CCQDER research, each respondent must provide basic informed consent to be interviewed and to have the interview recorded. In the case of respondents who are minors, basic consent includes informed consent which is obtained from the minor's parent or guardian as well as informed assent which is obtained from the minor respondent. The informed consent/assent statement that each respondent reads and signs indicates that the respondent's participation is voluntary and that the respondent can terminate the interview at any time without forfeiting any compensation that may have been promised (based on the study design of the particular project). This basic informed consent also specifies that CCQDER, QDRL contractor staff, and other project-specific collaborators and survey staff may be able to view interview recordings. Finally, the basic informed consent statement discloses that voice and facial identifiers will remain on the recording and acknowledges that the respondent may be recognized by anyone who views or listens to a recording

in the course of working on the project. If a respondent does not agree to these terms, they will receive the incentive, but the interview will not be conducted.

Future use consent: In addition to basic interview consent, respondents are asked for consent to retain their interviews for future use. This future use consent allows for the respondent's data (the raw data of the recorded interview) to be used in future research that is directly related to the survey questions discussed in the interview but that is not necessarily related to the project the data was originally collected for. If a respondent does not grant consent for future research, the interview is conducted and the recording is maintained only through the conclusion of the project (determined by the submission of a final report or similar product).

Special Consent: Finally, respondents may also be asked to provide "Special Consent." The current special Consent allows interviews to be shown outside of the QDRL and/or to audiences other than CCQDER, QDRL contractor staff, and project-specific collaborators. Special consent specifies use at conferences and trainings as well as viewing within the QDRL by researchers who are not CCQDER staff or contractors. Special Consent is obtained from an adult respondent after the interview is completed by having the respondent read and sign the Special Consent for Expanded Use of Video and Audio Recordings form. Special Consent is not requested of those respondents who opt out of the future research consent and respondents under the age of 18.

Recension of consent: Any respondent, regardless of the type of consent they have given, may contact the CCQDER at any time to rescind their consent. When a respondent rescinds consent, any recording of that respondent will be immediately destroyed.

Consent form storage: Each consent form is labeled with an identification number linking it to the associated recording and stored in a locked filing cabinet until it is digitally scanned. After they are scanned, the paper consent forms are destroyed and the digital files are stored on the secure QDRL LAN.

2. Restricted Interviews:

Another factor that determines an interview's retention status is whether the interview is labeled as *restricted* or not. Restricted interviews are those that carry more serious implications associated with disclosure and which require enhanced data retention and storage protections. There are three types of *restricted* interviews:

- a. *Child self-report*: Recorded interviews of respondents under age 18 years, or minors, are designated as restricted.
- b. <u>Adult proxy for Child</u>: A proxy-respondent is a respondent who answers on behalf of another person. Recorded interviews of adult proxy-respondents who are answering on behalf of a minor (under the age of 18 years).
- c. <u>The topic of interview is about illegal behaviors</u>: Recorded interviews pertaining to illegal behaviors committed by the respondent or a proxy are considered restricted. A designation is made between those projects with interview questions that ask respondents to report illegal behaviors verses those that do not. Illegal behaviors, including but not limited to illegal drug use and impaired driving, are those that are clearly defined by law and are punishable if disclosed. Because of the subjectivity of theoretically "sensitive" topics and because respondents provide informed consent based on the disclosed interview topic, interviews on behaviors that some may deem as embarrassing or disconcerting are not restricted.

Restricted interviews, defined by the terms above, require enhanced protections for data storage and retention. Interviews that are given the restricted designation are stripped of video upon project completion by designated CCQDER staff and maintained only in audio format. The audience for restricted interviews is limited, and they are reviewed more frequently by the CCQDER Director and CCQDER project-specific staff to determine whether the interview continues to have qualitative value for use in federal question evaluation research projects or activities.

Retention Status Categories

As stated above, an interview's retention status pertains to 1) the persons permitted access to the recording, 2) the required media format for its storage, and 3) the permitted retention time for its recording. These categories are stipulated by the project and interview-level factors discussed above and are demarcated within the Retention Status Matrix presented below.

1. **Viewing Access**: The determination regarding the persons who are eligible to view a recording and under which circumstances. There are 7 potential audiences:

With basic consent

- a. Internal project related: CCQDER and QDRL contractor staff viewing within the QDRL related to a specific project.
- b. Collaborator: Shown by CCQDER staff, inside the QDRL, for researchers collaborating on the specific project as named in the consent. This type of audience is relevant through the duration of the project. In the chance that a respondent chooses to terminate the interview, collaborators are permitted to view recorded interviews only; they are not permitted to watch live interviews.
- c. Project specific training: Shown by CCQDER staff, outside of the QDRL, to interviewers who will be conducting interviews for the specific project. This type of audience is relevant only when a project is running.

With future use consent

d. Internal research related: CCQDER and QDRL contractor staff viewing within the QDRL related to general question evaluation research rather than to a specific project.

With both future use and special consent

- e. Conferences: Shown by CCQDER staff, outside of the QDRL, to a general audience of conference attendees.
- f. Classroom Training: Shown by CCQDER staff, outside of the QDRL, to students learning to conduct cognitive interviewing studies.
- g. Research Interests: Shown by CCQDER staff, inside the QDRL, to researchers not associated with a specific project but who have a viable question-evaluation research purpose for accessing specific interviews.
- 2. Stored Data Format: Recordings may be stored as either video with audio or audio-only. The CCQDER has a routine set of administrative, technical, and physical measures to safeguard video and audio recordings. The QDRL LAN is not located on either the NCHS or CDC LAN, and the QDRL LAN is inaccessible to others (not CCQDER personnel/QDRL contractors) inside or outside NCHS. Storage of video and audio recordings on the QDRL LAN are protected through use of passwords and carefully restricted access. Only authorized personnel are allowed access to video and audio recordings and only when their work requires it. Personnel holding proper passwords may access the QDRL LAN through their QDRL Computer Desk Top which is hardwired to the QDRL

LAN (but which is not connected to any other network). When recordings are shown outside of the secure QDRL area, they are transported and stored on encrypted thumb drives.

3. **Data Retention Period:** Data retention specifies length of time the recording may be retained. The data retention period for recordings of interviews that do not have consent for future use is until the completion of the project (upon completion of a final product or final sponsor briefing). Upon project completion, these non-retained recordings will be destroyed by designated CCQDER staff. For those interviews being maintained for future use, the data retention period for storing the interview recording will begin after the conclusion of each project (upon completion of a final product or final sponsor briefing). Restricted recordings will have an initial retention period of 2 years after project completion, and non-restricted recordings will have an initial retention period of 5 years after project completion. After the initial retention period, the recordings will be re-evaluated by the CCODER Director to determine relevance, ongoing usefulness, and qualitative value for likely use in question evaluation research. If it is determined by the CCQDER Director in conjunction with CCODER project-relevant staff that there is no valid reason to retain the recording, it will be destroyed by designated CCQDER staff. If the interview continues to be of value (defined as ongoing use by research staff, topic relevance, likely use for federal questions evaluation research), reassessment of the recording will occur again in either 2 years (for restricted interviews) or 5 years (for unrestricted interviews).

Interview Retention Status Matrix

Retention Status	With Specia	al Consent*	Without Spec	No future use	
Categories	Unrestricted Interview	Restricted Interview+	Unrestricted Interview	Restricted Interview+	consent^
Viewing Audience	 Internal project related Collaborator Project specific training Internal research related Research Interests Conferences Classroom Training 	 Internal project related Collaborator Project-Specific Training Internal Research Related Research Interests 	 Internal project related Collaborator Project-Specific Training 	 Internal project related Collaborator Project-Specific Training 	NA
Stored Data Type	Video or Audio	Audio only	Video or Audio	Audio only	Destroyed
Data Retention Reviewing Period	Assessed every 5 Years	Assessed every 2 Years	Assessed every 5 Years	Assessed every 2 Years	NA

^{*}Interviews for which special consent has been obtained

Protocol for Determination, Maintenance and Safeguarding of Interview Recordings

^{**}Interviews for which special consent was not obtained either because it was not asked (minors or designated projects) or because special consent was not granted by the respondent

[^]Interviews with no future use consent are not maintained.

⁺Restricted interviews consist of interviews conducted with minors, adult proxy for minors, and/or those pertaining to illegal behavior (i.e. self-reported or proxy reported).

Each interview will receive a retention status based on both respondent and project level considerations and defined within the Retention Status Matrix. ERB packages will denote whether a project falls into the restricted or unrestricted designation. If the research requires a different policy than indicated by the matrix, a justification will be provided at that time.

All consent forms presented to the respondent at the beginning of the interview will disclose the eligible viewing audience, the recording type as well as the terms for data retention for the particular project. Informed consent documents contain the sentence "When the interview is finished, you may watch/listen to the recording." If after viewing or listening to the recording, the respondent rescinds his/her earlier consent to be recorded or to have his/her recording retained the recording is destroyed. If a respondent chooses to terminate the interview, they will be asked for consent to retain the completed portion of the interview. If the respondent does not grant consent, the interview will be destroyed. Respondents are also given a copy of the form, containing information about how to contact the CCQDER Laboratory Manager, the NCHS Research Ethics Review Board Chair, and the NCHS Confidentiality Officer.

In cases where Special Consent is requested, the respondent is asked for Special Consent at the end of the interview and after receipt of remuneration. The special consent statement discloses the audience and retention terms specific to the particular project. If the respondent grants Special Consent, he/she is told that if for any reason they change their mind, they should contact the laboratory manager by calling or writing to change the status of the recording. If a respondent does not grant Special Consent, the respondent is informed that the recording will only be seen or heard by CCQDER staff, QDRL contractor staff working as designated agents on behalf of the CCQDER, or direct study collaborators, which is described in the initial informed consent form.

Each interview recording will be assigned a unique identifier, which specifies the respondent, the project and the retention status of the particular recording. The unique identifier will be assigned by the lab manager immediately after the interview when the recording is saved. With this approach, the status will always be attached to the recording.

After the analysis has been conducted at the conclusion of each project (as determined by the submission of a final report or similar product), interviews with no future use consent or special consent will be destroyed. Additionally, restricted interviews determined to be stored as audio-files will be stripped of video. The period of data retention will commence from the time of this distinction and reviewed according to their retention classification. Assessment of recordings will be every 2 to 5 years (depending on the particular review period) using the QDRL Outlook Calendar.

Recordings that are shown outside of the QDRL will be temporarily transported and stored on an encrypted thumb drive which is only accessible by the specific CCQDER researcher to which it was issued. The warning, "Recording of this material is prohibited," will be included in presentation materials (e.g.PowerPoint or presentation slides) when recordings are shown outside of the QDRL, for example as part of conference presentations.

At roughly a month in advance of the 2 or 5 year review period, interviews will be evaluated on the criteria of 1) current research using the project data since last review 2) current relevance of questions evaluated and 3) qualitative value for likely use in question evaluation research. If any of the 3 criteria are met, the interview will be kept with a renewed retention period, and re-evaluated every 2- or 5- years according to the assigned retention status. Rationales for retaining interviews must be attached to each interview media file to serve as an audit trail. A report documenting the number of interviews retained and destroyed will be produced annually by CCQDER staff.

Recordings of interviews from past CCQDER projects are currently stored in accordance with the consent guidelines that were in effect when they were created. After adoption of the new data retention and storage plan, these stored files will be identified and assessed according to the new policy. This new assessment will take place after CCQDER files have been migrated to the new software system (which is expected facilitate the implementation of the policy).

Attachment A - Template 1 (as referred to in generic package)

Informed consent/Adults

[written at an 8th grade reading level]

(waived signed informed consent may be submitted as part of an amendment when seeking approval for a particular study on sensitive topics for which waived informed consent is requested.)



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

Adult 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 well being 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 topic(s)].

Your interview will show us how to improve the questions for this 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 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 [duration], and we will give you \$XX. 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 Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) and [FILL DIVISION OR AGENCY] who are working on the project may [watch/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 5448, 3311 Toledo Rd., Hyattsville, MD 20782.

Recordings

We would like to video/audio¹ 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/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. Only researchers from the CCQDER and [FILL DIVISION OR AGENCY] working on

the project will be allowed to [watch/listen to] the recording in a secured room. When in use all recordings will be in the safe keeping of a staff person from the CCQDER.

You may decide at any time after the interview that you don't want us to keep a recording of the interview. In this case, you may contact Karen Whitaker by phone at (301) 458-4569, or by mail at NCHS, Room 5448, 3311 Toledo Rd., Hyattsville, MD 20782. When she receives your request, the recording of your interview will be immediately destroyed.

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, only staff and collaborators working directly on this project will be allowed to [watch/listen to] the recording. The recorded interview will be destroyed at the end of the project unless you agree to let us keep it longer.

Privacy

We are required by law² 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 CCQDER 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 or those viewing the audiovisual recording or audio recording, however, may recognize you or your voice.

If you have questions about National Center for Health Statistics privacy' laws and practices, contact the NCHS Confidentiality Office by phone at 888-642-4159 or 301-458-4601, or by email at nchsconfidentiality@cdc.gov.

Benefits and Risks

There are no 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 \$XX.

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 800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol #2016-16-29. 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.

When video recording is selected:

I allow NCHS to video record my interview. I also allow NCHS to play my video recording to other people working on this project on-site at NCHS CCQDER.

• 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. I also allow NCHS to play my video recording to interested researchers on-site at NCHS CCQDER. I understand that the recording of my interview will be kept for as long as it is of interest to researchers (a minimum of two years).

Yes
 No



When audio recording is selected:

I allow NCHS to audio record my interview. I also allow NCHS to play my audio recording to other people working on this project on-site at NCHS CCQDER.

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. I also allow NCHS to play my audio recording to interested researchers on-site at NCHS CCQDER. I understand that the recording of my interview will be kept for as long as it is of interest to researchers (a minimum of two years).

• Yes • No

Respondent Signature	Print name	Date

¹Either video or audio will be selected.

²The Public Health Service Act provides us with the authority to do this research (42 U.S.C. 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 U.S.C. 242m(d)) and the Confidential Information Protection and Statistical Efficiency Act (Title III, Pub. L. No. 115-435, 132 Stat. 5529).

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 Reports Clearance Officer; 1600 Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0222).

OMB #0920-0222; Expiration Date: 08/31/2021

Attachment A - Template 2 (as referred to in generic package)
Informed consent for minors/Parental & Guardian form
[written at an 8th grade reading level]
(informed assent for minors form will be submitted as part of an amendment when seeking approval for a particular study including minors.)



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 Parental/Guardian Permission for One-on-one Interviews

Your child is being asked to take part in a research study. This consent form tells you about the study and what your child will be asked to do. You can choose to have your child take part in the study or not. If you permit your child to take part, you will need to sign this form. Your child will also have a consent form to read and sign.

Purpose of the Research

Surveys are used to collect information on the health and well being 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 permit your child to take part in this test, we will ask your child to answer the survey questions. Then, we will ask your child to explain what he/she was thinking and how he/she came up with their answers.

The questions that we are working on today are about [fill topic(s)].

Your child's interview will show us how to improve the questions for this survey. In the future, we may also study your child's 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 your child some survey questions. Then, the interviewer will ask your child to explain what he/she was thinking as he/she answered the questions. The interviewer will ask your child if there were any words that were confusing and if he/she understood what was being asked.

The interview will last [duration], and we will give your child \$XX. In order to receive the \$XX, you will need to fill out the attached cash payment receipt form. The form is attached for your review. We also ask that you fill out for your child a personal information sheet.

Your child may find that some of the questions we are testing are sensitive. He/she may choose not to answer any question for any reason. If he/she does not want to answer a question, he/she can say so, and we will move on to the next one. Your child may also stop the interview at any time. While the interview is going on, researchers from the Center for Questionnaire Design Research and Evaluation (CCQDER) and [FILL DIVISION OR AGENCY] who are working on the project may [watch/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 5448, 3311 Toledo Rd., Hyattsville, MD 20782.

Recordings

We would like to audio record¹ your child's 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 your child's interview recorded. If you agree, your child may still ask to stop the recording at any time, and we will turn off the machine. If your child decides to stop the recording, we will ask his/her consent to retain the portion already recorded. When the interview is finished, your child may also [watch/listen to] the recording. You will not be allowed to watch/listen to the interviewing while it is being recorded or watch/listen to the recording at a later time.

If you agree to record your child's 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. Only researchers from the CCQDER and [fill] working on the project will be allowed to [watch/listen to] the recording in a secured room. When in use all recordings will be in the safe keeping of a staff person from the CCQDER. The recorded interview will be destroyed at the end of the project unless you agree to let us keep it longer.

You may decide at any time after the interview that you don't want us to keep a recording of the interview. In this case, you may contact Karen Whitaker by phone at (301) 458-4569, or by mail at NCHS, Room 5448, 3311 Toledo Rd., Hyattsville, MD 20782. When she receives your request, the recording of your interview will be immediately destroyed.

Privacy

We are required by law² to tell you what we will do with your child's recording. We must also tell you how we will protect your child's 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 child's name or other personal facts.

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

Your child's name or other personal facts that would identify your child will not be used when we discuss or write about this study. People working on this project or those viewing the audiovisual recordings or audio recording, however, may recognize your child or your child's voice.

If you have questions about National Center for Health Statistics privacy' laws and practices, contact the NCHS Confidentiality Office by phone at 888-642-4159 or 301-458-4601, or by email at nchsconfidentiality@cdc.gov.

Benefits and Risks

There are no 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 child's privacy. Your child does not have to give us any information that he/she does not want to, and he/she can choose not to answer any question in the interview. He/she may also stop at any time and still receive the full \$XX.

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 800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol #2016-16-29. Your call will be returned as soon as possible.

Please Read and Sign Below if You Agree

• I allow my child to take part in this research study.

I allow NCHS to audio record his/her interview. I also allow NCHS to play his/her audio recording to other people working on this project on-site at NCHS CCQDER.

Yes
 No

IF YES:

I allow NCHS to retain his/her 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. I also allow NCHS to play my audio recording to interested researchers on-site at NCHS CCQDER. I understand that the recording of my child's interview will be kept for as long as it is of interest to researchers (a minimum of two years).

Yes
 No

Parent or Guardian	Print name	Date	
¹ The Public Health Service Act provides a permit identification of any individual, a ponly by NCHS staff, contractors, and ager other persons without the consent of the ir Act (42 U.S.C. 242m(d)) and the Confidential Stat. 5529).	oractice, or an establishment will be l	held confidential, will be us	ed for statistical purposes
	nts only when required and with nece	essary controls, and will not	be disclosed or released to
	ndividual or the establishment in acco	ordance with section 308(d)	of the Public Health Service
Public reporting burden for this collection of in instructions, searching existing data sources, g. An agency may not conduct or sponsor, and a OMB control number. Send comments regard reducing this burden, to CDC/ATSDR Reports	athering and maintaining the data needec	l, and completing and reviewir	ng the collection of information.
	person is not required to respond to, a co	llection of information unless	it displays a currently valid
	ing this burden estimate or any other asp	ect of this collection of inform	ation, including suggestions for

OMB #0920-0222; Expiration Date: 08/31/2021



Attachment A - Template 3 (as referred to in generic package) [written at an 8th grade reading level] Informed consent/Off-site

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 Conducted Off-site

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 well being 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 topic(s)].

Your interview will show us how to improve the questions for this 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 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 [duration], and we will give you \$XX. 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.

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 5448, 3311 Toledo Rd., Hyattsville, MD 20782.

Recordings

We would like to video/audio¹ 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/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. Only researchers from the Collaborating Center for Questionnaire Design (CCQDER) and [fill] working on the project will be allowed to [watch/listen to] the recording in a secured room. When in use all recordings will be in the safe keeping of a staff person from the CCQDER. The recorded interview will be destroyed at the end of the project unless you agree to let us keep it longer.

You may decide at any time after the interview that you don't want us to keep a recording of the interview. In this case, you may contact Karen Whitaker by phone at (301) 458-4569, or by mail at NCHS, Room 5448, 3311 Toledo Rd., Hyattsville, MD 20782. When she receives your request, the recording of your interview will be immediately destroyed.

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, only staff and collaborators working directly on this project will be allowed to [watch/listen to] the recording

Privacy

We are required by law² 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 CCQDER 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 or those viewing the audiovisual recording or audio recording, however, may recognize you or your voice.

If you have questions about National Center for Health Statistics privacy' laws and practices, contact the NCHS Confidentiality Office by phone at 888-642-4159 or 301-485-4601, or by email at nchsconfidentiality@cdc.gov.

Benefits and Risks³

There are no 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 \$XX.

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 National Center for Health Statistics.

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 800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol #2016-16-29. 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.

When video recording is selected:

I allow NCHS to video record my interview. I also allow NCHS to play my video recording to other people working on this project on-site at NCHS CCQDER.

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. I also allow NCHS to play my video recording to interested researchers on-site at NCHS CCQDER. I understand that the recording of my interview will be kept for as long as it is of interest to researchers (a minimum of two years).

• Yes • No

When audio recording is selected:

I allow NCHS to audio record my interview. I also allow NCHS to play my audio recording to other people working on this project on-site at NCHS CCQDER.

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. I also allow NCHS to play my audio recording to interested researchers on-site at NCHS CCQDER. I understand that the recording of my interview will be kept for as long as it is of interest to researchers (a minimum of two years).

Yes
 No

Respondent Signature	Print name	Date

²The Public Health Service Act provides us with the authority to do this research (42 U.S.C. 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 U.S.C. 242m(d)) and the Confidential Information Protection and Statistical Efficiency Act (Title III, Pub. L. No. 115-435, 132 Stat. 5529).

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 Reports Clearance Officer; 1600 Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0222).

OMB #0920-0222; Expiration Date: 08/31/2021

¹Either video or audio will be selected.

Attachment A -Template 4 (as referred to in generic package) Informed consent/Focus groups [written at an 8th grade reading level]



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 Focus Groups

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 well being 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, you will be part of a discussion group about new questions for [FILL survey name here].

The discussion group will show us how to improve the questions for this survey. In the future, we may also study the group 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

A group leader will ask you to share your thoughts and ideas about the questions with other people in the group. You will <u>not</u> be asked your personal answers to the questions. We will ask you to pick a name and put it on a name tag. You do not have to use your real name.

The discussion will last XX minutes, and we will give you \$XX. You will be asked to fill out a personal information sheet.

You may leave the discussion group at any time. You may also choose not to discuss any question for any reason. While the discussion is going on, researchers from the Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) and [FILL DIVISION OR AGENCY] who are working on the project may watch the discussion.

If you have any questions about how the project works, contact Karen Whitaker by phone at (301) 458-4569, or by mail at NCHS, Room 5448, 3311 Toledo Road, Hyattsville, MD 20782.

Recordings

We plan to video/audio¹ record the discussion. 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 discussion recorded. When the discussion is finished, you or anyone in the group may watch/listen to the recording. Recording is essential for this project. If you do not wish to be recorded, you should not join the discussion. If you decide that you do not want to be recorded, you will still receive the full \$XX. The recorded interview will be destroyed at the end of the project unless all members of the focus group agree to let us keep it longer.

Recordings are kept in a locked room, either in a secure storage cabinet or on a password-secured computer that is not connected to the internet. Only researchers from CCQDER and [FILL AGENCY/DIVISION] working on the project will be allowed to [watch/listen to] the recording in a secured room. When in use, all recordings will be in the safe keeping of a staff person from the CCQDER.

You may decide at any time after the interview that you don't want us to keep a recording of the interview. In this case, you may contact Karen Whitaker by phone at (301) 458-4569, or by mail at NCHS, Room 5448, 3311 Toledo Rd., Hyattsville, MD 20782. When she receives your request, the recording of your interview will be immediately destroyed.

At the end of the discussion, we may ask you for special permission to play the recording in a more public setting. For example, the discussion could be played for students who want to learn how to write survey questions. If you or any of the other members of the focus group do not agree to this special permission, only staff and collaborators working directly on this project will be allowed to [watch/listen to] the recording.

Privacy

We are required by law² 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 CCQDER 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 or those viewing the audiovisual recording or audio recording, however, may recognize you or your voice.

If you have questions about National Center for Health Statistics privacy' laws and practices, contact the NCHS Confidentiality Office by phone at 888-642-4159 or 301-458-4601, or by email at nchsconfidentiality@cdc.gov.

Benefits and Risks

There are no 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 discussion. You may also stop at any time and still receive the full \$XX.

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 800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol #2016-16-29. 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 discussion group.

When video recording is selected:

I allow the National Center for Health Statistics to video record me. I also allow NCHS to show the video recording to other people working on this project on-site at NCHS CCQDER.

• Yes • No

IF YES:

I allow the National Center for Health Statistics 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. I also allow NCHS to play my video recording to interested researchers on-site at NCHS CCQDER. I understand that the recording of my interview will be kept for as long as it is of interest to researchers (a minimum of two years).

• Yes • No

When	audio	recording	is	selected:
4 4 11C11	uuuio	I C C O I CI II I	10	ociccica.

I allow the National Center for Health Statistics to audio record me. I also allow NCHS to play the audio recording to other people working on this project on-site at NCHS CCQDER.

• Yes • No

IF YES:

I allow the National Center for Health Statistics 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. I also allow NCHS to play my audio recording to interested researchers on-site at NCHS CCQDER. I understand that the recording of my interview will be kept for as long as it is of interest to researchers (a minimum of two years).

• Yes • No

Participant Signature	Print name	Date

²The Public Health Service Act provides us with the authority to do this research (42 U.S.C. 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 U.S.C. 242m) and the Confidential Information Protection and Statistical Efficiency Act (Title III, Pub. L. No. 115-435, 132 Stat. 5529).

¹Either video or audio will be selected.



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

OMB #0920-0222; Expiration Date: 8/31/2021

Special Consent for Expanded Use of Video and Audio Recordings

Purpose

The National Center for Health Statistics' (NCHS), Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) staff often presents what we learn from our projects at training sessions. We would like your permission to show this recording to those who are interested in survey questions but who are not working directly on this project. If you agree, we may show the recording to students, or to other people who write survey questions. In these cases, the recording is always under the control of CCQDER staff who have signed non-disclosure agreements.

Why do we want to show the recordings?

The recordings show how people react to survey questions. They show how questions can be hard to understand or hard to answer. They help people write better survey questions. It may also teach other researchers how to test survey questions.

Where might the recordings be shown?

We may show parts of the recording in a small meeting room, a classroom, or a large group at a professional meeting.

What information will be on the recording?

The whole recording could be shown. But it is more likely that a short piece will be shown about a problem with a question. No information about you will be added to the recording. However, your face and/or voice will appear on the recording and you may be recognized.

How long will the recording be kept?

The recording will be kept for as long as it is of interest to researchers (a minimum of five years). Every five years, the recording will be reassessed, and if it is no longer useful, it will be destroyed.

What if I say yes now, but change my mind later?

If you change your mind, contact Karen Whitaker by phone at (301) 458-4569, or by mail at NCHS, Room 5448, 3311 Toledo Rd., Hyattsville, MD 20782. You may change your mind at any time. When she receives your request, we will not allow special uses of your recording.

Questions

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 800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol #2016-16-29. Your call will be returned as soon as possible.

If you have questions about National Center for Health Statistics privacy' laws and practices, contact the NCHS Confidentiality the Office by phone at 888-642-4159 or 301-458-4601, or by email at nchsconfidentiality@cdc.gov.

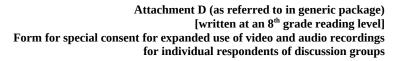
Either video recording or audio recording will be selected

When video recording is selected:

If You Agree, Please Read and Sign Below

• I allow the National Center for Health Statistics to show my video recording to students, and to other people who write survey questions. I understand that my face and/or voice will appear on the recording. The recording will not be altered. The recording will be in the control of CCQDER staff. If I change my mind at any time, I will contact Karen Whitaker, the NCHS Lab Manager.

• I do not allow National Center for F	Health Statistics to use my video record	ing in this way.	
When audio recording is selected:			
If You Agree, Please Read and Sign B	Below		
questions. I understand that my voi	Statistics to play my audio recording to ice will appear on the recording. The rechange my mind at any time, I will cont	cording will not be altered. The re	cording will be in
• I do not allow National Center for Health Statistics to use my audio recording in this way.			
Respondent Signature	Print name	Date	





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

OMB #0920-0222; Expiration Date: 8/31/2021

Special Consent for Expanded Use of Video and Audio Recordings for Individual Respondents of Discussion Groups

Purpose

The National Center for Health Statistics' (NCHS), Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) staff often presents what we learn from our projects at conferences, professional meetings, or training sessions. We would like your permission to show the group discussion recording to those who are interested in survey questions but who are not working directly on this project. If you agree, we may show the recording at conferences, for students, or for other people who write survey questions. In these cases, the recording is always under the control of CCQDER staff.

Why do we want to show the recordings?

The recordings show how people react to survey questions. They show how questions can be hard to understand or hard to answer. They help people write better survey questions. It may also teach other researchers how to test survey questions.

Where might the recordings be shown?

We may show parts of the recording in a small meeting room, a classroom, or a large group at a professional meeting.

What information will be on the recording?

The whole recording could be shown. But it is more likely that a short piece will be shown about a problem with a question. No information about you will be added to the recording. However, your face and/or voice will appear on the recording. Someone might be able to identify you through the recording.

How long will the recording be kept?

The recording will be kept for as long as it is of interest to researchers (a minimum of five years). Every five years, the recording will be reassessed, and if it is no longer useful, it will be destroyed.

What if I say yes now, but change my mind later?

If you change your mind, contact Karen Whitaker by phone at (301) 458-4569, or by mail at NCHS, Room 5448, 3311 Toledo Rd., Hyattsville, MD 20782. You may change your mind at any time. When she receives your request, she will edit the recording to erase any section in which you are heard or seen.

Questions

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 800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol #2016-16-29. Your call will be returned as soon as possible. Your call will be returned as soon as possible.

If you have questions about National Center for Health Statistics privacy' laws and practices, contact the NCHS Confidentiality Office by phone at 888-642-4159 or 301-458-4601, or by email at nchsconfidentiality@cdc.gov.

Either video recording or audio recording will be selected

When video recording is selected:

If You Agree, Please Read and Sign Below

• I allow the National Center for Health Statistics to show my video recording to students, and to other people who write survey questions. I understand that my face and/or voice will appear on the recording. The recording will not be altered. The recording

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Pa	articipant Signature Print name Date
	I do not allow National Center for Health Statistics to use my audio recording in this way.
	I allow National Center for Health Statistics to play my audio recording to students, and to other people who write survey questions. I understand that my voice will appear on the recording. The recording will not be altered. The recording will be in the control of CCQDER staff. If I change my mind at any time, I will contact Karen Whitaker, the NCHS Lab Manager.
f	You Agree, Please Read and Sign Below
N]	Then audio recording is selected:
	I do not allow National Center for Health Statistics to use my video recording in this way.
	will be in the control of CCQDER staff. If I change my mind at any time, I will contact Karen Whitaker, the NCHS Lab Manager.