

Attachment 12 – Adult informed consent for interviews conducted face-to-face



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 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 study, 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 new diabetes medications and other health topics.

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**

A member of the CCQDER research team, either a staff interviewer or a contracted interviewer from Research Support Services (RSS), 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 [\$50]. You will also be asked to fill out a personal information sheet. The information sheet will be stored on a secure server and only CCQDER and RSS researchers working on the study will have access to the sheet. Your information will be kept for up to 5 years and you can decide at any time to be removed from our database. Email recruitmentteam@cdc.gov to request removal.

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 RSS contractors who are working on the project may [watch/listen to] the interview.¹

If you have questions about how the project works, contact CCQDER by email at recruitmentteam@cdc.gov.

Recordings

We would like to video/audio² 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 who work on this project from the CCQDER, RSS contractors, National Center for Chronic Disease Prevention and Health Promotion/Division of Diabetes Translation (NCCDPHP/DDT), and NCHS's Division of Research and Methodology (DRM) 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. In accordance with the CCQDER Data Storage and Access Policy, upon project completion, the video of the interview will be destroyed. Audio recordings will be retained for a minimum 5 years and may be used for question evaluation research that is not directly related to this project.

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 CCQDER by email at recruitmentteam@cdc.gov. When we receive your request, the recording of your interview will be immediately destroyed.

- **Privacy**

We are required by law³ 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 stored on a password secure server and will be kept up to five years in a locked room. Only CCQDER staff has access to this material. Any hardcopies of these materials will be destroyed upon completion of your interview. Project related information will be stored in our database for up to five years, located on password protected and secure server. You may decide at any time after the interview that you don't want us to keep your information. In this case, you may contact CCQDER by email at recruitmentteam@cdc.gov to request removal. When CCQDER receives your request, your personal information and recording of your interview will be immediately destroyed.

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 direct benefits to you 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 location⁴

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 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 Project ID-XX [Note: The project ID will be inserted into the form once CDC IRB 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.

When video recording is selected:

I allow NCHS to video record my interview. I also allow NCHS to play my video recording to researchers who work on this project from CCQDER, DRM, NCCDPHP/DDT, and RSS 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 internal NCHS CCQDER staff. I understand that the recording of my interview will be kept for as long as it is of interest to researchers (a minimum of five 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 researchers who work on this project from CCQDER, DRM, NCCDPHP/DDT, and RSS 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 internal NCHS CCQDER staff. I understand that the recording of my interview will be kept for as long as it is of interest to researchers (a minimum of five years).

☐ Yes ☐ No

Respondent Signature

Print Name

Date

¹This paragraph will be included in the consent form for those interviews conducted at the Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER).

²Either video or audio will be selected.

³The Public Health Service Act provides us with the authority to do this research (42 U.S.C 242k). We take your privacy very seriously. 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 U.S.C. 242m(d)) and the Confidential Information Protection and Statistical Efficiency Act or CIPSEA (44 U.S.C. 3561-3583). In accordance with CIPSEA, every NCHS employee, contractor, and 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. In addition to the above cited laws, NCHS complies with the Federal Cybersecurity Enhancement Act of 2015 (6 U.S.C. §§ 151 and 151 note) which protects Federal information systems from cybersecurity risks by screening their networks.

⁴This paragraph will be included in the consent form for those interviews conducted offsite.

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 H21-8, Atlanta, GA 30333, ATTN: PRA (0920-0222).

OMB #0920-0222; Expiration Date: 01/31/2026

Attachment 12: Adult informed consent for interviews conducted virtually



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 Virtual 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 read this entire 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 study, 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 new diabetes medications and other health topics.

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**

This interview will be conducted virtually through videoconferencing software. NCHS secures all information we collect, process and store on our systems as required by Federal regulations, Executive Orders, and NCHS confidentiality statutes. However, NCHS cannot secure and protect your personal computing devices, such as personal computer or smart phones, used to complete the NCHS interview. During the interview, a member of the CCQDER research team, either a staff interviewer or a contracted interviewer from Research Support Services (RSS), 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 email you the link to your [\$50 electronic gift card]. You will also be asked demographic questions from 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 CCQDER by email at recruitmentteam@cdc.gov.

- **Recordings**

We would like to video record your interview. The recording allows us to more carefully study and improve the questions. If you agree, you may still ask to stop the recording at any time, and we will stop recording. If you decide to stop recording, we will ask your consent to retain the portion already recorded.

We will keep the recording of your interview in a locked room either in a secure storage cabinet or on a password-secured computer. Only researchers who work on this project from the CCQDER, RSS contractors, National Center for Chronic Disease Prevention and Health Promotion/Division of Diabetes Translation (NCCDPHP/DDT) and NCHS's Division of Research and Methodology (DRM) will be allowed to watch the recording. When in use all recordings will be in the safe keeping of a staff person from the CCQDER. In accordance with the CCQDER Data Storage and Access Policy, upon project completion, the video of the interview will be destroyed. Audio recordings will be retained for a minimum of 5 years and may be used for question evaluation research that is not directly related to this project.

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 CCQDER by email at recruitmentteam@cdc.gov. When we receive your request, the recording of your interview will be immediately destroyed.

- **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.

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 or password protected. 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 direct benefits to you 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]. NCHS secures all information we collect, process and store on our systems as required by Federal regulations, Executive Orders, and NCHS confidentiality statutes. However, NCHS cannot secure and protect your personal computing devices, such as personal computer or smart phones, used to complete the NCHS interview.

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 Project ID:XXXX [Note: The project ID will be inserted into the form once CDC IRB approval has been received]. Your call will be returned as soon as possible.

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¹The Public Health Service Act provides us with the authority to do this research (42 U.S.C 242k). We take your privacy very seriously. 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 U.S.C. 242m(d)) and the Confidential Information Protection and Statistical Efficiency Act or CIPSEA (44 U.S.C. 3561-3583). In accordance with CIPSEA, every NCHS employee, contractor, and 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. In addition to the above cited laws, NCHS complies with the Federal Cybersecurity Enhancement Act of 2015 (6 U.S.C. §§ 151 and 151 note) which protects Federal information systems from cybersecurity risks by screening their networks.

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 H21-8, Atlanta, GA 30333, ATTN: PRA (0920-0222).

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