

Attachment E - Template 1

Adult Informed consent for One-on-one Interviews conducted face-to-face

[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 conducted face-to-face**

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

Purpose of the Research

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

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

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

Your interview will show us how to improve 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/A member of the CCQDER research team, either a staff interviewer or a contracted interviewer from [fill], 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 [60/90] minutes, and we will give you [\$40/\$50/\$other]. 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), [fill] contractors, and [fill division or agency/testing partners, etc.] who are working on the project may [watch/listen to] the interview.

If you have questions about how the project works, contact Ms. Amanda Titus by phone at (301) 458-4579, or by mail at NCHS, Room 5470, 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, [fill] contractors, and [fill division agency/testing partners] who are 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 Amanda Titus by phone at (301) 458-4579, or by mail at NCHS, Room 5470, 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 CCQDER staff, [fill] contractors, and [fill] 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 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 [\$40/\$50/\$other].

If you have any questions about this study, please call the office of the Research Ethics Review Board at the National Center for Health Statistics, toll-free at 1-800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol #XXXX-XX-XX [Note: The amendment number will be inserted into the form once NCHS ERB approval has been received]. Your call will be returned as soon as possible.

Please Read and Sign Below if You Agree

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

When video recording is selected:

I allow NCHS to video record my interview. I also allow NCHS to play my video recording to researchers from CCQDER, [fill] contractors and [fill division agency/testing partners] 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 [two/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 from CCQDER, [fill] contractors, and [fill division agency/testing partners] 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 [two/five] 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 of the Foundations for Evidence-Based Policymaking Act of 2018 (Pub. L. No. 115-435, 132 Stat. 5529 § 302)). 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.

Public reporting burden for this collection of information is estimated to average [60/90] 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 E Template 2
Adult Informed consent for One-on-one Interviews Conducted Off-site
[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 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 wellbeing of Americans. The surveys help to develop programs to improve the health and health care of people living in the United States.

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

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

Your interview will show us how to improve 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/A member of the CCQDER research team, either a staff interviewer or a contracted interviewer from [fill], 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 [60/90] minutes, and we will give you [\$40/\$50/\$other]. 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. Amanda Titus by phone at (301) 458-4579, or by mail at NCHS, Room 5470, 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, [fill] contractors, and [fill division agency/testing partners] who are 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 Amanda Titus by phone at (301) 458-4579, or by mail at NCHS, Room 5470, 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 CCQDER staff, [fill] contractors, and [fill] 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 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 [\$40/\$50/\$other].

Conducting an interview at a mutual location³

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 1-800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol #XXXX-XX-XX [Note: The amendment number will be inserted into the form once NCHS ERB approval has been received]. Your call will be returned as soon as possible.

Please Read and Sign Below if You Agree

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

When video recording is selected:

I allow NCHS to video record my interview. I also allow NCHS to play my video recording to researchers from CCQDER, [fill] contractors and [fill division agency/testing partners] 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 [two/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 from CCQDER, [fill] contractors, and [fill division agency/testing partners] 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 [two/five] 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 of the Foundations for Evidence-Based Policymaking Act of 2018 (Pub. L. No. 115-435, 132 Stat. 5529 § 302)). 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.

³This 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 [60/90] 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 E -Template 3
Informed consent/Focus groups**



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 not 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 90 minutes, and we will give you \$[fill]. You will also 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), [fill] contractors, and [fill division or agency/testing partners, etc.] who are working on the project may [watch/listen to] the interview.

If you have any questions about how the project works, contact Amanda Titus by phone at (301) 458-4579, or by mail at NCHS, Room 5470, 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 \$[fill].

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 the CCQDER, [fill] contractors, and [fill division agency/testing partners] who are 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).

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 at a conference or for students who want to learn how to write survey questions. If you do not agree to this special permission, we will not allow anyone other than the staff working directly on this project 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 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 discussion. You may also stop at any time and still receive the full \$[fill].

If you have any questions about this study, please call the office of the Research Ethics Review Board at the National Center for Health Statistics, toll-free at 1-800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol #XXXX-XX-XX [Note: The protocol number and the amendment number will be inserted into the form once NCHS ERB approval has been received]. Your call will be returned as soon as possible.

Please Read and Sign Below if You Agree

- I freely choose to take part in this discussion group.

When video recording is selected:

I allow NCHS to video record me. I also allow NCHS to play my video recording to researchers from CCQDER, [fill] contractors and [fill division agency/testing partners] 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 [two/five] years).

- Yes
- No

When audio recording is selected:

I allow NCHS to audio record me. I also allow NCHS to play my audio recording to researchers from CCQDER, [fill] contractors and [fill division agency/testing partners] 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 [two/five] years).

- Yes
- No

Participant 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 of the Foundations for Evidence-Based Policymaking Act of 2018 (Pub. L. No. 115-435, 132 Stat. 5529 § 302)). 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.

Public reporting burden for this collection of information is estimated to average [60/90] 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 E - Template 4

Adult Informed consent for One-on-one Interviews conducted virtually [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 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 test, we will ask you to answer the survey questions. Then, we will ask you to explain what you were thinking and how you came up with your answers.

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

Your interview will show us how to improve 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 [fill], 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 [60/90] minutes, and we will mail you [\$40/\$50/\$other]. 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 Ms. Amanda Titus by phone at (301) 458-4579, or by mail at NCHS, Room 5470, 3311 Toledo Rd., Hyattsville, MD 20782.

Recordings

We would like to video record your interview. The recording allows us to more carefully study and improve the questions. 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 from the (CCQDER), [fill] contractors, and [fill division agency/testing partners] who are working on the project 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, recordings will be retained for a minimum of [2/5 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 Amanda Titus by phone at (301) 458-4579, or by mail at NCHS, Room 5470, 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 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 [\$40/\$50/\$other]. 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 Research Ethics Review Board at the National Center for Health Statistics, toll-free at 1-800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol #XXXX-XX-XX [Note: The amendment number will be inserted into the form once NCHS ERB approval has been received]. Your call will be returned as soon as possible.

¹The 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 of the Foundations for Evidence-Based Policymaking Act of 2018 (Pub. L. No. 115-435, 132 Stat. 5529 § 302)). 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.

Public reporting burden for this collection of information is estimated to average [60/90] 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 E - Template 5
Informed consent for minors/Parental & Guardian form
[written at an 8th grade reading level]
(informed consent 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. A member of the CCQDER research team, either a staff interviewer or a contracted interviewer from [fill], 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 no more than [60/90] minutes, and we will give you [\$40/\$50/\$other]. You will also be asked to fill out 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 Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER), [fill] contractors, and [fill division or agency/testing partners, etc.], who are working on the project may [watch/listen to] the interview.

If you have questions about how the project works, contact Ms. Amanda Titus by phone at (301) 458-4579, or by mail at NCHS, Room 5470, 3311 Toledo Rd., Hyattsville, MD 20782.

Recordings

We would like to video/audio¹ record 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 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, [fill] contractors, and [fill division or agency/testing partners, etc.] who are 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.

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 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 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, 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 direct benefits to your child 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 [\$40/\$50/\$other].

If you have any questions about this study, please call the office of the Research Ethics Review Board at the National Center for Health Statistics, toll-free at 1-800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol #XXXX-XX-XX [Note: The protocol number and the amendment number will be inserted into the form once NCHS ERB approval has been received]. Your call will be returned as soon as possible.

Please Read and Sign Below if You Agree

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

When video recording is selected:

I allow NCHS to video record his/her interview. I also allow NCHS to play his/her video recording to researchers from CCQDER, [fill] contractors and [fill division agency/testing partners] on-site at NCHS CCQDER.

- Yes
- No

IF YES:

I allow NCHS to retain his/her 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 his/her video recording to internal NCHS CCQDER staff. I understand that the recording of his/her interview will be kept for as long as it is of interest to researchers (a minimum of [two/five] years).

- Yes
- No

When audio recording is selected:

I allow NCHS to audio record his/her interview. I also allow NCHS to play his/her audio recording to researchers from CCQDER, [fill] contractors and [fill division agency/testing partners] 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 his/her video recording to internal NCHS CCQDER staff. I understand that the recording of his/her interview will be kept for as long as it is of interest to researchers (a minimum of [two/five] years).

- Yes
- No

Parent or Guardian

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 of the Foundations for Evidence-Based Policymaking Act of 2018 (Pub. L. No. 115-435, 132 Stat. 5529 § 302)). 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.

Public reporting burden for this collection of information is estimated to average [60/90] 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).

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