

(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

Informed Consent Form
QDRL 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 like you. 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 these questions. In the future, we may also study your interview along with interviews from other projects. This type of study will teach us about the different kinds of problems people have answering survey questions. The study will help us write better questions in the future.

Procedures

An interviewer will ask you 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. In order to receive the \$XX, you will need to fill out a cash payment receipt form. 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 [FILL AGENCY] who are working with us on this 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 3225, 3311 Toledo Rd., Hyattsville, MD 20782.

Recordings

We would like to video/audio¹ record your interview. The recording allows us to more carefully study 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 ask to stop the recording at any time, and we will turn off the machine. If you decide to stop taping, we will ask your consent to retain the portion already taped.

If you agree to record the interview, we will keep it in a locked room or in the safe keeping of a staff person from the

Questionnaire Design Research Laboratory (QDRL). At a later time, staff from the [FILL AGENCY] who are responsible for developing questions on these topics may [watch/listen to] the interview. However, they must agree to keep your personal data private. Also, they must [watch/listen to] the interview in the QDRL or with QDRL staff present.

At the end of the interview, we may ask you for special permission to play the recording in a more public setting. For example, the interview could be played at a conference or for students who want to learn how to write survey questions. If you do not agree to this special permission, we will not allow anyone other than 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 QDRL staff have access to this material.

Your name or other personal facts that would identify you will not be used when we discuss or write about this study. People working on this project, however, may recognize you or your voice.

If you have questions about NCHS privacy laws and practices, contact Eve Powell-Griner, Ph.D., Confidentiality Officer at 1-888-642-4159.

Benefits and Risks

Other than the \$XX you receive, there are no other direct benefits from taking part in this study.

The possible risks of taking part in this study are minimal. We will take all possible steps to protect your privacy. You do not have to give us any information that you do not want to, and you can choose not to answer any question in the interview. You may also stop at any time and still receive the full \$XX.

If you have any questions about this study, please call the office of the Ethics Review Board at the National Center for Health Statistics, toll-free at 1-800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol #2010-19-XX [Note: The 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 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 either in the QDRL or in another location under the direct supervision of QDRL staff.
- I do not allow NCHS to video record my interview.

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 either in the QDRL or in another location under the direct supervision of QDRL staff.
- I do not allow NCHS to audio record my interview.

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 United States Code 242k). All information which would permit identification of any individual, a practice, or an establishment will be held confidential, will be used only by NCHS staff, contractors, and agents only when required and with necessary controls, and will not be disclosed or released to other persons without the consent of the individual or the establishment in accordance with section 308(d) of the Public Health Service Act (42 USC 242m) and the Confidential Information Protection and Statistical Efficiency Act (PL-107-347).

Public reporting burden for this collection of information is estimated to average XX 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: [fill date]

Attachment D - Template 2
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

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3311 Toledo Road
Hyattsville, Maryland 20782

Informed Consent Form
Parental/Guardian Permission

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 like your child. 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].

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 [FILL AGENCY] who are working with us on this 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 3225, 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 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 ask to stop the recording at any time, and we will turn off the machine. If your child decides to stop taping, we will ask his/her consent to retain the portion already taped. When the interview is finished, your child may also

[watch/listen to] the recording. So that your child feels comfortable answering the questions, 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 or in the safe keeping of a staff person from the Questionnaire Design Research Laboratory (QDRL). At a later time, staff from the [FILL AGENCY] who are responsible for developing questions on these topics may watch the interview. However, they must agree to keep your child's personal data private. Also, they must [watch/listen to] the interview in the QDRL or with QDRL staff present.

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 name or other personal facts.

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

Your 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 NCHS privacy laws and practices, contact Eve Powell-Griner, Ph.D., Confidentiality Officer at 1-888-642-4159.

Benefits and Risks

Other than the \$XX your child receives, there are no other direct benefits from taking part in this study.

The possible risks of taking part in this study are minimal. We will take all possible steps to protect your 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 1-800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol #2010-19-XX [Note: The 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 other people working on this project either in the QDRL or in another location under the direct supervision of QDRL staff.
- I do not allow NCHS to video record his/her interview.

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 other people working on this project either in the QDRL or in another location under the direct supervision of QDRL staff.
- I do not allow NCHS to audio record his/her interview.

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 United States Code 242k). All information which would permit identification of any individual, a practice, or an establishment will be held confidential, will be used only by NCHS staff, contractors, and agents only when required and with necessary controls, and will not be disclosed or released to other persons without the consent of the individual or the establishment in accordance with section 308(d) of the Public Health Service Act (42 USC 242m) and the Confidential Information Protection and Statistical Efficiency Act (PL-107-347).

Public reporting burden for this collection of information is estimated to average XX 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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DEPARTMENT OF HEALTH & HUMAN SERVICES

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National Center for Health Statistics
3311 Toledo Road
Hyattsville, Maryland 20782

**Informed Consent Form
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 like you. 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 XX minutes, and we will give you \$XX. In order to receive the \$XX, you will need to fill out the attached cash payment receipt form. 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 [FILL AGENCY] who are working with us on this 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 3225, 3311 Toledo Road, Hyattsville, MD 20782.

Recordings

We plan to video/audio¹ record the discussion. The recording allows us to more carefully study 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.

Recordings are kept in a locked room or in the safe keeping of a staff person from the Questionnaire Design Research

Laboratory (QDRL). At a later time, staff from the [FILL AGENCY] who are responsible for developing questions on these topics may [watch/listen to] the interview. However, they must agree to keep your personal data private. Also, they must [watch/listen to] the interview in the QDRL or with QDRL staff present.

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 QDRL staff have access to this material.

Your name or other personal facts that would identify you will not be used when we discuss or write about this study. People working on this project, however, may recognize you or your voice.

If you have questions about NCHS privacy laws and practices, contact Eve Powell-Griner, Ph.D., Confidentiality Officer at 1-888-642-4159.

Benefits and Risks

Other than the \$XX you receive, there are no other direct benefits from taking part in this study.

The possible risks of taking part in this study are minimal. We will take all possible steps to protect your privacy. You do not have to give us any information that you do not want to, and you can choose not to answer any question in the 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 1-800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol #2010-19-XX [Note: The 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 the video recording to other people working on this project either in the QDRL or in another location under the direct supervision of QDRL staff.
- I do not allow NCHS video record me.

When audio recording is selected:

- I allow NCHS to audio record me. I also allow NCHS to play the audio recording to other people working on this project either in the QDRL or in another location under the direct supervision of QDRL staff.
- I do not allow NCHS audio record me.

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 United States Code 242k). All information which would permit identification of any individual, a practice, or an establishment will be held confidential, will be used only by NCHS staff, contractors, and agents only when required and with necessary controls, and will not be disclosed or released to other persons without the consent of the individual or the establishment in accordance with section 308(d) of the Public Health Service Act (42 USC 242m) and the Confidential Information Protection and Statistical Efficiency Act (PL-107-347).

Public reporting burden for this collection of information is estimated to average XX 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: [fill 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

Informed Consent Form
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 like you. 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. 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. In order to receive the \$XX, you will need to fill out the attached cash payment receipt form. 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 [FILL AGENCY] who are working with us on this 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 3225, 3311 Toledo Rd., Hyattsville, MD 20782.

Recordings

We would like to video/audio¹ record your interview. The recording allows us to more carefully study 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 ask to stop the recording at any time, and we will turn off the machine. If you decide to stop taping, we will ask your consent to retain the portion already taped.

If you agree to record the interview, we will keep it in a locked room or in the safe keeping of a staff person from the Questionnaire Design Research Laboratory (QDRL). At a later time, staff from [FILL AGENCY] who are responsible for developing questions on these topics may [watch/listen to] the interview. However, they must agree to keep your

personal data private. Also, they must [watch/listen to] the interview in the QDRL or with QDRL staff present.

At the end of the interview, we may ask you for special permission to play the recording in a more public setting. For example, the interview could be played at a conference or for students who want to learn how to write survey questions. If you do not agree to this special permission, we will not allow anyone other than 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 QDRL staff have access to this material.

Your name or other personal facts that would identify you will not be used when we discuss or write about this study. People working on this project, however, may recognize you or your voice.

If you have questions about NCHS privacy laws and practices, contact Eve Powell-Griner, Ph.D., Confidentiality Officer at 1-888-642-4159.

Benefits and Risks³

Other than the \$XX you receive, there are no other direct benefits from taking part in this study.

The possible risks of taking part in this study are minimal. We will take all possible steps to protect your privacy. You do not have to give us any information that you do not want to, and you can choose not to answer any question in the interview. You may also stop at any time and still receive the full \$XX.

Conducting an interview at a business location

The interview will be conducted in a closed office. We will protect any materials that contain your personal information and transport them to NCHS.

Conducting a home interview

In order for you to take part in the study today, we agreed to come to your home. Meeting in your home 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 NCHS.

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 #2010-19-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 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 either in the QDRL or in another location under the direct supervision of QDRL staff.
- I do not allow NCHS to video record my interview.

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 either in the QDRL or in another location under the direct supervision of QDRL staff.
- I do not allow NCHS to audio record my interview.

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 United States Code 242k). All information which would permit identification of any individual, a practice, or an establishment will be held confidential, will be used only by NCHS staff, contractors, and agents only when required and with necessary controls, and will not be disclosed or released to other persons without the consent of the individual or the establishment in accordance with section 308(d) of the Public Health Service Act (42 USC 242m) and the Confidential Information Protection and Statistical Efficiency Act (PL-107-347).

³Depending on the study, select either *conducting an interview at a business location* or *conducting a home interview*.

 Public reporting burden for this collection of information is estimated to average XX 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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