### Attachment 4a – Adult Informed Consent for self-responder



## **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 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 head or neck injuries.

Your interview will show us how to improve the questions for this survey. In the future, we may also study your interview along with interviews from other projects. This type of study will teach us about the different kinds of problems people have answering survey questions. The study will help us write better questions in the future.

### **Procedures**

An interviewer will ask you some survey questions. Then, the interviewer will ask you to explain what you were thinking as you answered the questions. The interviewer will ask you if there were any words that were confusing and if you understood what was being asked.

The interview will last no more than 60 minutes, and we will give you \$40. 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 Center for Questionnaire Design and Evaluation Research (CQDER) and the National Center for Injury Prevention and Control, who are working on the project may [watch/listen to] the interview.

If you have questions about how the project works, contact Ms. Karen Whitaker by phone at (301) 458-4569, or by mail at NCHS, Room 6330, 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. When in use all recordings will be in the safe keeping of a staff person from the Center for Questionnaire Design and Evaluation Research (CQDER).

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 law<sup>2</sup> 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 CQDER 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, 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**

There are no 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 \$40.

Conducting an interview at a mutual location<sup>3</sup>

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 #2010-19-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 other people working on this project either in the CQDER or in another location under the direct supervision of CQDER staff.
• 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.
• Yes • No
When audio recording is selected:
I allow NCHS to audio record my interview. I also allow NCHS to play my audio recording to other people working on this project either in the CQDER or in another location under the direct supervision of CQDER staff.
• Yes • No
IF YES: I allow NCHS to retain my audio recording for future research on how people react to survey questions and how survey questions can be hard to understand or hard to answer.
• Yes • No
Participant Signature Print name Date
<sup>1</sup> Either video or audio will be selected.
<sup>2</sup> The Public Health Service Act provides us with the authority to do this research (42 United States Code 242k). All information which would permit identification of any individual, a practice, or an establishment will be held confidential, wi 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 accordanc 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).
<sup>3</sup> This paragraph will be included in the consent form for those interviews conducted offsite.

## Attachment 4b: Combined Adult and Parental/Guardian Informed consent



## **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

# Combined Informed Consent Form For Adult and Parental/Guardian Permission

You and your child are being asked to take part in a research study. This consent form tells you about the study and what you and your child will be asked to do. You can choose to take part and chose to have your child take part in the study or not. If you choose to take part and 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 take part and permit your child to take part in this test, we will ask you and your child to answer the survey questions. Then, we will ask you and your child to explain what you and your child were thinking and how you and your child came up with the answers.

The questions that we are working on today are about head or neck injuries.

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

Your and your child's interview will last 60 minutes each, and we will give you and your child each \$40. We also ask that you fill out a personal information sheet.

You and your child may find that some of the questions we are testing are sensitive. You and your child may choose not to answer any question for any reason. If you and your child do not want to answer a question, you and your child can say so, and we will move on to the next one. You and your child may also stop the interview at any time. While the interview is going on, researchers from the Center for Questionnaire Design and Evaluation Research (CQDER) and the National Center for Injury Prevention and Control, who are working on the project may [watch/listen to] the interview.

If you have questions about how the project works, contact Ms. Karen Whitaker by phone at (301) 458-4569, or by mail at NCHS, Room 6330, 3311 Toledo Rd., Hyattsville, MD 20782.

# Recordings

We would like to video/audio¹ record your and 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 and your child's interview recorded. If you agree, you and your child may ask to stop the recording at any time, and we will turn off the machine. If you or your child decides to stop recording, we will ask consent to retain the portion already recorded. When the interview is finished, you may [watch/listen to] your recording and your child may [watch/listen to] their recording. You will not be allowed to watch/listen to your child's interview while it is being recorded or watch/listen to the recording at a later time.

If you agree to record your and your child's interview, we will keep it in a locked room either in a secure cabinet or on a password-secured computer that is not connected to the internet. When in use, all recordings will be in the safe keeping of a staff person from the Center for Questionnaire Design and Evaluation Research (CQDER).

# **Privacy**

We are required by law<sup>2</sup> to tell you what we will do with your and your child's recordings. We must also tell you how we will protect your and 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 or 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 CQDER staff have access to this material.

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

There are no 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 and your child's privacy. You and your child do not have to give us any information that you and your child do not want to, and you and your child can choose not to answer any question in the interview. You and your child may also stop at any time and you and your child will still receive the full \$40 each.

Conducting an interview at a mutual location<sup>3</sup>

In order for you and your child 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 and your child will feel comfortable answering the questions. We will protect any materials that contain your personal information and transport them to the Centers for Disease Control and Prevention's National Center for Health Statistics.

If you have any questions about this study, please call the office of the 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 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, and I allow my child to take part in this research study.

When video recording is selected:

I allow NCHS to video record my and my child's interview. I also allow NCHS to play my and my child's video recording to other people working on this project either in the CQDER or in another location under the direct supervision of CQDER staff.

• Yes • No

IF YES:

I allow NCHS to retain my and my child's 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.

• Yes • No

When audio recording is selected:

I allow NCHS to audio record my and my child's interview. I also allow NCHS to play my and my child's audio recording to other people working on this project either in the CQDER or in another location under the direct supervision of CQDER staff.

• Yes • No

IF YES:

I allow NCHS to retain my and my child's audio recording for future research on how people react to survey questions and how survey questions can be hard to understand or hard to answer.

• Yes • No

Participant Signature Print name Date

<sup>2</sup>The Public Health Service Act provides us with the authority to do this research (42 United States Code 242k). All information which would permit identification of any individual, a practice, or an establishment will be held confidential, will be used for statistical purposes only by NCHS staff, contractors, and agents only when required and with necessary controls, and will not be disclosed or released to other persons without the consent of the individual or the establishment in accordance with section 308(d) of the Public Health Service Act (42 USC 242m) and the Confidential Information Protection and Statistical Efficiency Act (PL-107-347).

<sup>3</sup>This paragraph will be included in the consent form for those interviews conducted offsite.

<sup>&</sup>lt;sup>1</sup>Either video or audio will be selected.

## Attachment 4c - Form for informed assent for minors/Minor form



# **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 Assent Form Teens (aged 12-17) One-on-one Interviews

Your parent or guardian says you can 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**

One way that the National Center for Health Statistics learns about health in this country is to ask people questions on surveys. Before we do that, we want to test the questions out on people of different backgrounds. We are interested in learning how well the questions work. Whether they make sense, are easy or hard to answer. There is no right or wrong answer to these questions.

The questions that we are working on today are about head and neck injuries.

## **Procedures**

An interviewer will ask you the survey questions and have you answer. Then, the interviewer will ask you some follow-up questions about how you came up with your answers. The interviewer will ask you if the questions were clear, and if any terms were confusing.

The interview will last no more than 60 minutes, and we will give you \$40.

You may find that some of the questions we are testing ask about sensitive issues. 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 Center for Questionnaire Design and Evaluation Research (CQDER) and the National Center for Injury Prevention and Control, who are working on the project may [watch/listen to] the interview.

If you have questions about how the project works, contact Ms. Karen Whitaker by phone at (301) 458-4569, or by mail at NCHS, Room 6330, 3311 Toledo Rd., Hyattsville, MD 20782.

## Recordings

We would like to video/audio¹ record your interview. The recording allows us to review what you said about 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 recording, we will ask your consent to retain what we have already recorded.

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. When in use all recordings will be in the safe keeping of a staff person from the Center for Questionnaire Design and Evaluation Research (CQDER).

#### **Privacy**

We are required by law<sup>2</sup> 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 CQDER 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**

There are no 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 \$40.

Conducting an interview at a mutual location<sup>3</sup>

In order for you to take part in the study today, we agreed to meet at this location. Meeting at this location is your choice. However, you are urged to choose a place that is private so that you will feel comfortable answering the questions. We will protect any materials that contain your personal information and transport them to the Centers for Disease Control and Prevention's National Center for Health Statistics.

If you have any questions about this study, please call the office of the 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 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 CQDER or in another location under the direct supervision of CQDER staff.

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.

• Yes • No

When audio recording is selected:

I allow NCHS to audio record my interview. I also allow NCHS to play my audio recording to other people working on this project either in the CQDER or in another location under the direct supervision of CQDER staff.

• Yes • No

IF YES:

I allow NCHS to retain my audio recording for future research on how people react to survey questions and how survey questions can be hard to understand or hard to answer.

• Yes • No

Participant Signature	 Print name	 Date
Participant Signature	Print name	Date

<sup>&</sup>lt;sup>1</sup>Either video or audio will be selected.

<sup>&</sup>lt;sup>2</sup>The Public Health Service Act provides us with the authority to do this research (42 United States Code 242k). All information which would permit identification of any individual, a practice, or an establishment will be held confidential, will be used for statistical purposes only by NCHS staff, contractors, and agents only when required and with necessary controls, and will not be disclosed or released to other persons without the consent of the individual or the establishment in accordance with section 308(d) of the Public Health Service Act (42 USC 242m) and the Confidential Information Protection and Statistical Efficiency Act (PL-107-347).

<sup>&</sup>lt;sup>3</sup>This paragraph will be included in the consent form for those interviews conducted offsite.