

Attachment 2 – Adult 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

Adult 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

The National Health and Nutrition Examination Survey, or NHANES, produces the data that is used to create growth charts used across the United States. In an effort to update these growth charts for use in cases of severe obesity, The National Center for Health Statistics (NCHS), one of the Centers for Disease Control and Prevention (CDC) has proposed a new methodology for combining multiple years of NHANES data. However, NCHS also wants to understand whether and how these new charts would be useful to pediatricians who work with patients who have high BMIs.

If you agree to take part in this test, you will be part of a discussion group about the use growth charts in clinical situations and what guidance NCHS should consider when releasing new growth charts. The discussion group will show us how to design and improve the language and format of these growth charts.

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 understanding the data products that are developed from surveys. The study will help us design better surveys and survey data products in the future.

Procedures

A group leader will ask you to share your thoughts and ideas about the growth charts with other people in the group. 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 \$150. You will be asked to fill out a personal information sheet.

You may leave the discussion group at any time. You may also choose not to discuss any question for any reason. While the discussion is going on, researchers from the Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) and the Division of Health and Nutrition Examination Surveys (DHNES) at the National Center for Health Statistics (NCHS) who are working on the project may watch/listen to the discussion.

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

Recordings

We plan to video/audio¹ record the discussion. The recording allows us to more carefully study the discussion. 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 \$150.

Recordings are kept in a locked room, either in a secure storage cabinet or on a password-secured computer that is not connected to the internet. Only researchers from CCQDER and DHNES 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 CCQDER.

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, however, may recognize you or your voice.

If you have questions about National Center for Health Statistics privacy³ 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 \$150.

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. 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 #2016-16-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 the focus group. I also allow NCHS to play the video recording to CCQDER and DHNES researchers working on this project on-site at NCHS CCQDER.

- Yes
- No

IF YES:

I allow NCHS to retain the video recording for future research on how people react to survey questions and products and how survey questions and products can be hard to answer or understand. I also allow NCHS to play the video recording to interested researchers on-site at NCHS CCQDER. I understand that the recording will be kept for as long as it is of interest to researchers (a minimum of two years).

- Yes
- No

When audio recording is selected:

I allow NCHS to audio record the focus group. I also allow NCHS to play the audio recording to CCQDER and DHNES researchers working on this project on-site at NCHS CCQDER.

- Yes
- No

IF YES:

I allow NCHS to retain the audio recording for future research on how people react to survey questions and products and how survey questions and products can be hard to answer or understand. I also allow NCHS to play the audio recording to interested researchers on-site at NCHS CCQDER. I understand that the recording will be kept for as long as it is of interest to researchers (a minimum of two years).

- Yes
- No

Respondent Signature

Print name

Date

¹Either video or audio will be selected.

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

³This paragraph will be included in the consent form for those focus group conducted offsite.