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

January 17, 2020

Margo Schwab, Ph.D.
Office of Management and Budget
725 17th Street, N.W.
Washington, DC 20503

Dear Dr. Schwab:

The staff at the National Center for Health Statistics (NCHS) Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) (OMB No. 0920-0222, exp. 08/31/2021), plans to conduct a series of focus group discussions with pediatricians about proposed additions to the CDC-approved BMI (body mass index, kg/m2) growth charts for children aged 2 to 20. This proposed project is being conducted on behalf of NCHS' Division of Health and Nutrition Examination Surveys (DHNES), following work DHNES and the Division of Research and Methodology completed to improve the accuracy of tracking children and adolescents with extreme values of body mass index.

The current growth charts, which were last revised in 2000, include data from National Health Examination Survey (NHES) II and III and National Health and Nutrition Examination Survey (NHANES) I, II, and III spanning 1972-1994. They display a series of percentile curves, with the largest being the 97th percentile. Unfortunately, tracking of the Body Mass Index (BMI) above the 97th percentile is statistically unreliable. This is particularly important as the percentage of children with extreme BMI has increased in the last 2 decades. In an attempt to rectify this, DHNES has considered a number of alternative BMI metrics, and has proposed an extended BMI z-score (or extended "BMIz") that incorporates more recent NHANES data from 1988-2016 for respondents at or above the obesity cut point.

While the draft charts that incorporate this BMIz are mathematically valid, the question remains whether NCHS/CDC should release accompanying guidance on the naming of these extended lines, and if so, what that guidance should be. In order to obtain the perspective of clinical pediatricians who will use these charts on a day-to-day basis, CCQDER proposes a series of up to five focus group discussions about how participants may use these extended charts and the naming conventions they would find clinically helpful.

We propose to recruit up to 40 pediatricians to participate in up to 5 focus groups. We would aim to have a maximum of 8 participants per focus group. CCQDER and DHNES will work jointly to recruit the focus group participants, and no recruitment ad will be used. Focus Groups will be limited to 90 minutes. The outline of the protocol to be used in these focus groups is included as Attachment 1, and the procedure conforms to the techniques that have been described in our generic package (0920-0222).

Focus groups will be conducted by CCQDER staff and will be held in the Questionnaire Design and Evaluation Research Laboratory as well as at off-site locations. All groups conducted in the Questionnaire Design and Evaluation Research Laboratory will be video

and audio recorded to allow researchers to review the behaviors and body language of the respondents. Groups conducted off-site will only be audio recorded. These recordings will allow researchers to ensure the quality of their notes. Due to the group nature of the discussions, in the rare case that a study participant initially agrees to audio or video recording during the telephone screening, but changes their mind and checks "no" to allowing the focus group to be recorded on the informed consent document the focus group will proceed with audio recording with the other participants, and the individual who changed his or her mind will be released. They will still receive the remuneration proposed below. Individuals who select "yes" for allowing the audio recording on the informed consent form, but "no" for retaining the recording for future research (final text before signatures on informed consent form), will be allowed to participate in the study. In this case, the recording for the focus group will be treated as though all members of the group answered "no" to this question, and the file will be destroyed at the end of the project.

After participants have been briefed on the purpose of the study and the procedures that CCQDER routinely takes to protect human subjects, participants will be asked to read and sign an Informed Consent document (Attachment 2). Participants will also be asked to fill in their demographic characteristics on the Respondent Data Collection Sheet (Attachment 3).

The facilitators will then ask each participant to confirm that he/she understands the information in the Informed Consent, and then state that we would like to record the focus group. The recorder will be turned on once the procedures are understood and agreed upon. We will not be asking for Special Consent for Expanded Use of Video and Audio Recordings with this project because of the group nature of the study.

After the focus group, participants will be given the thank-you letter signed by the Acting Director of NCHS (Attachment 4), a copy of the informed consent document, and $150. We propose a higher-than usual renumeration for this project as we are a) dealing with a specialized, and difficult-to-recruit population of interest (pediatricians, particularly those working in obesity clinics or centers), b) conducting focus groups, which require multiple participants to align their schedules, and c) are proposing a 90-minute interview (inclusive of both the respondent data collection sheet found in Attachment 3 and the focus group discussion itself).

Extreme care will be taken with all recordings and paperwork from the focus groups conducted off-site. Recordings and identifying paperwork will be stored in a secured travel case until returned to NCHS, at which point they will be transferred to the usual secured locked storage cabinets.

FOR FOCUS GROUPS WITH VIDEO RECORDING:
Upon project completion of the project video recordings will be stripped of the video by designated CCQDER staff and maintained only in audio format. Initial retention period of the audio recordings is 2 years after project completion. After the initial retention period, the recordings will be re-evaluated by the CCQDER Director to determine relevance, ongoing usefulness, and qualitative value for likely use in question evaluation research. If it is determined by the CCQDER Director in conjunction with CCQDER project-relevant staff that there is no valid reason to retain the recording, it will be destroyed by designated CCQDER staff. If the interview continues to be of value (defined as ongoing use by research staff, topic relevance, likely use for federal questions evaluation research), reassessment of the recording will occur again in 2 years.

FOR FOCUS GROUPS WITH AUDIO-ONLY RECORDING:
Initial retention period of the audio recordings is 2 years after project completion. After the initial retention period, the recordings will be re-evaluated by the CCQDER Director to

determine relevance, ongoing usefulness, and qualitative value for likely use in question evaluation research. If it is determined by the CCQDER Director in conjunction with CCQDER project-relevant staff that there is no valid reason to retain the recording, it will be destroyed by designated CCQDER staff. If the interview continues to be of value (defined as ongoing use by research staff, topic relevance, likely use for federal questions evaluation research), reassessment of the recording will occur again in 2 years.

Project Burden

Shown below is the table for the focus groups that consist of 60 total burden hours:

Form Name	**Number of Participants**	**Number of Responses/ Participant**	**Average hours per response**	**Response Burden (in hours)**
Respondent Data Collection Sheet	40	1	5/60	3
Focus Group Discussion	40	1	85/60	57
Total				60

Attachments (4)
cc:
Summer King
Jeff Zirger
DHHS RCO