

Supporting Statement A for Request for Clearance:
**COLLABORATING CENTER FOR QUESTIONNAIRE
DESIGN AND EVALUATION RESEARCH**

NHIS Diabetes Focus Group and Cognitive Testing Project

OMB No. 0920-0222

Expiration Date: 01/31/2026

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A. JUSTIFICATION

1. **Circumstances Making the Collection of Information Necessary**

The NCHS Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) conducts qualitative and mixed method research. CCQDER data collection is authorized under a generic OMB clearance (OMB No. 0920-0222, Exp. Date 01/31/2026) and 42 U.S.C. 242k (Section 306 of the Public Health Service Act).

2. **Purpose and Use of Information Collection**

CCQDER conducts exploratory question evaluation studies, for both applied and methodological purposes, with particular focus on question design, measurement, comparability, and response error.

The purpose of the current GLP-1 RA (diabetic injectable medication) Focus Group and

Cognitive Testing Project is to develop and rigorously test of a question set related to new GLP-1 RA injectable medications. The proposed approach includes focus groups and cognitive testing. The project will be carried out in collaboration with Centers for Disease Control and Prevention (CDC)'s National Center for Chronic Disease Prevention and Health Promotion/Division of Diabetes Translation (NCCDPHP/DDT).

Within the last 10 years, GLP-1 receptor agonists (GLP-1 RAs), originally used for type 2 diabetes management, have been applied to help lower blood sugar and promote weight loss, which can reduce the risk of developing diabetes complications, such as cardiovascular disease (CVD), stroke, kidney disease, and blindness (Michos et al. 2023). Consequently, GLP-1 RAs recently received FDA approval for obesity treatment and CVD prevention, leading to increases in popularity and utilization, as well as supply shortages and unintended health disparities. NCHS and DDT developed a new question on GLP-1 injectable use among people with diabetes or prediabetes that was included as emerging content on the 2024 NHIS. DDT sponsored the question again for the 2025 NHIS.

Existing data sources offer data on the prevalence of GLP-1 RA use including NHANES, MEPS, EHRs, and other studies or databases with medication information. However, no known nationally representative data sources provide information about aspects related to GLP-1 RA such as overall awareness, knowledge, perceptions, stigma, affordability, accessibility, and disparities among population subgroups. Non-federal polls such as that conducted by the Kaiser Family Foundation have explored key questions of interest related to GLP-1 RA, but these have not been rigorously tested (KFF Health Tracking Poll, 2024). NHIS would be the ideal survey to add new content on GLP-1 RAs, as it serves as CDC DDT's key data source for annual trends in US diabetes prevalence and incidence and is nationally representative with a sample size large enough for subgroup analyses.

This GLP-1 RA Focus Group and Cognitive Testing Project will allow for the development and rigorous testing of a question set that can be used in future federal surveys and beyond. Specifically, with subject matter expert feedback, we will use a protocol with prioritized topics in the focus groups to identify the most appropriate language to use in writing the questions. Cognitive interviews will then be used to refine the questions and examine how the proposed questions capture the intended constructs. The final questions are intended for inclusion on the 2026 NHIS to allow for a deeper understanding beyond current use of GLP-1 RAs among the US population, those with diabetes, and those with other conditions. The data from these questions present many public health surveillance and research opportunities not only for diabetes primary and secondary prevention but chronic disease prevention and management, in general.

Focus Groups Procedures:

Recruiting: We propose to recruit up to 48 English-speaking adults (aged 18 or over) from a variety of racial and educational backgrounds for up to 6 focus groups in 2 cities (3 groups per city). Focus groups will be structured to include participants with similar characteristics with regards to their diabetes status, obesity, and GLP-1 medication use. The newspaper advertisement/flyer used to recruit respondents is shown in Attachment 2. A 5-minute screener will be used to determine eligibility of individuals responding to the newspaper advertisements/flyers is shown in Attachment 3. It is anticipated that as many as 80 individuals

may need to be screened in order to recruit 48 focus group participants.

Focus Groups will be limited to 90 minutes. The outline of the protocol to be used in these focus groups is included as Attachment 4. The focus groups will be conducted by CCQDER staff or contractors and will take place either in-person in a private location or virtually, via video conference through Zoom. The Zoom platform has been approved by CDC and NCHS Information Security Offices. If interviews cannot be conducted virtually, NCHS staff propose holding them in person in the Questionnaire Design Research Laboratory (QDRL) or off-site.

In-person: After participants have been briefed on the purpose of the focus groups and the procedures that CCQDER routinely takes to protect human subjects, respondents will be asked to read and sign an Informed Consent document (Attachment 5). Participants will also be asked to fill in their demographic characteristics on the Respondent Data Collection Sheet (Attachment 6).

Virtual: For virtual focus groups, participants and facilitators will see and hear each other through the video conference software from their own computer, tablet, or cellphone from their respective locations. A recruiter will meet the participants on the scheduled video conferencing appointment (through Zoom). The recruiter will make sure the participants are prepared for the focus group and that the video conferencing application is working properly. The recruiter will go over the informed consent information that was previously emailed to the participants (Attachment 5), remind the respondent of the remuneration procedure, and help ensure the Zoom software is working properly. Once the videoconferencing software is working properly, the recruiter will collect the information from the Respondent Data Collection Sheets (Attachment 6). At this point, the facilitator will join the video conference, and the recruiter will leave the meeting.

The facilitator will then ask the participants to confirm that he/she understands the information in the Informed Consent (Attachment 5), 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. Once the recording has started, the facilitator will confirm that the participants agreed to be recorded. The facilitator will confirm that the participants have agreed to be recorded by asking, *“Do you agree that the focus group will be video recorded? Yes, I agree or no, I don’t agree.”* At this point the facilitator will begin orienting the participants to the purpose of the discussion and begin, following the protocol outlined in Attachment 4.

Video/Audio Recording: Video or audio recording is required for this project. These recordings will allow researchers to review the behaviors and body language of the respondents and to ensure the quality of their focus group notes. Recordings will be used and retained in accordance with the CCQDER Data Storage and Access Policy (Attachment 8). Researchers from DRM, NCCDPHP/DDT, and CCQDER contractors will use the recordings for research purposes. CCQDER contractors viewing/listening to recordings in the QDRL under CCQDER supervision have read and signed a non-disclosure affidavit (Attachment 9) and completed confidentiality training.

In-person: All focus groups conducted in person will be video and/or audio recorded. In rare cases, a study participant may initially agree to be video recorded during the telephone screening but change their mind at the time of the focus group. If a participant changes their mind in the case of an in-person focus group, the participant will be asked if they agree to be audio recorded. If they decline to be audio recorded the focus group will proceed without recording. In these rare cases the requirement for audio recording will be relaxed and the facilitator will depend on their handwritten notes when conducting analysis.

Virtual: CCQDER will request permission to video record all virtual focus groups conducted via Zoom. If a participant consents to being video recorded and then changes their mind after the focus group has begun, the focus group will proceed with audio-only recording. In this case, the interviewer will instruct the participant to turn off their camera and explain that only audio will be recorded if the participant's camera remains off. If the participant's camera is turned back on, the interviewer will remind the respondent to turn the camera off if they do not want to be recorded. If they decline to be audio recorded the focus group will proceed without recording. In these rare cases the requirement for audio recording will be relaxed and the facilitator will depend on their handwritten notes when conducting analysis.

NCHS government issued encrypted laptops will be used to video and audio record the focus groups conducted off-site or virtually by both CCQDER researchers and contractors. Facilitators can then securely upload their focus group into CDC's Secure Access Management Services (SAMS) which has been approved by the ISSO to securely exchange electronic files containing confidential information. Recordings can then be downloaded by the SAMS/Q-Video Administrator onto an encrypted flash drive and then transferred to the CCQDER LAN. The recordings will then be deleted from SAMS. Alternatively, facilitators can use their NCHS government issued encrypted flash drive to transfer the recordings from their laptop to the CCQDER's secure LAN. The encrypted flash drive is FIPS 140-2 compliant and approved for use by OCISO.

Procedure for Sending Videos via SAMS and Uploading into Q-Video

1. All audio and video recordings of off-site and virtual focus groups will be saved to NCHS government issued encrypted laptops
2. Immediately after the focus group, the researcher will upload the saved file into the CDC SAMS environment ([Secure Access Management Service \(cdc.gov\)](https://www.cdc.gov/sams/))
3. The researcher will immediately delete the file from their NCHS government issued encrypted laptop
4. After the recordings are uploaded to CDC SAMS, a CCQDER technician with the proper background investigation level will transfer the files from CDC SAMS to the "Air-Gapped" Q-Video environment using the following procedure:
 - a. The CCQDER technician will transfer the files from SAMS to a CDC encrypted drive that has been provisioned by and is managed by CDC SafeConsole;
 - b. The CCQDER technician will then scan the CDC encrypted drive for threats using Windows Defender;

- c. The CCQDER technician will then disconnect the CDC encrypted drive from the CDC-issued laptop;
- d. The CCQDER technician will then connect the CDC encrypted drive to the Q-Video environment and transfer the focus group files;
- e. The CCQDER technician will then log the data transfers noting the name of CCQDER analyst, date of transfer, names of the files transferred, etc.
- f. The CCQDER technician will then ensure the data has been deleted from the CDC encrypted drive and disconnected from the Q-Video environment, which concludes the one-way data transfer process.

Extreme care will be taken with all recordings and paperwork from in person focus groups conducted off-site. Identifying paperwork will be stored in a secured travel case until returned to NCHS, at which point the identifying paperwork will be transferred to the usual secured locked storage cabinets. Once the video and audio recordings are transferred to the secure QDRL Network (Q-Video), the recording will be deleted from SAMS.

After the focus group: After the focus group, participants will be given the thank-you letter (Attachment 7) a copy of the informed consent document (Attachment 5), and \$100. (In the case of virtual focus groups, the participants will instead be sent a “thank you” email, informing them that they will receive a hard copy of the informed consent document and their remuneration amount (\$100) in cash via FedEx within 7 business days). If electronic gift cards are used for remuneration, the respondent will be emailed the activation code for the gift card with an electronic copy of the informed consent document.

Deletion of information: Once the focus group is complete and any remuneration has been sent, all email, phone call and calendar records for the participants will be deleted.

If a participant requests that their recording be destroyed at the end of the project, the recording will be destroyed at the end of the project which is defined as when a report has been cleared by NCHS. If all focus group participants give future consent, 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 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 focus group 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 5 years.

Cognitive Interviewing Procedures:

CCQDER will adhere to the cognitive research technique, also known as cognitive interviewing, to carry out testing procedures and identify any conceptual problems with the draft questions. The questions to be tested with cognitive interviewing will be developed based on the results of the focus groups. Interviews will take place either in-person in a private location or virtually, via video conference through Zoom. The Zoom platform has been approved by CDC and NCHS Information Security Offices. In the event that interviews cannot be conducted virtually, NCHS staff propose holding them in person in the Questionnaire Design Research Laboratory (QDRL) or off-site.

Recruiting: As many as 60 respondents will be recruited. Additionally, we aim to recruit respondents with a roughly even mix of age, race, educational attainment, and diabetes status, obesity, and GLP-1 medication use. The initial goal is to recruit groups in equal proportion, to the extent possible – that is, within the constraints of those willing to participate in the study. However, because qualitative sampling is based on theoretical relevance more than equal cell sizes, on-going analysis may reveal the need to recruit more from one group than others. Recruitment will be carried out through a combination of a newspaper advertisement, social media, flyers, word-of-mouth, and CCQDER Respondent Database. The newspaper advertisements/flyers used to recruit respondents are shown in Attachment 10.

Screening and Scheduling: After potential respondents contact the recruiter by phone or email, the recruiter will follow up to screen them for eligibility for inclusion in the study. The screener used to determine eligibility of individuals responding to the advertisement/flyer is shown in Attachment 11. During the screening process, recruiters will inform respondents of the consent form, video recording and remuneration procedures. Recruiters will also assess respondents' video conferencing capabilities and will assist in setting up the video conference application (Zoom). After respondents are scheduled, a confirmation email will be sent which will include information about the date and time of interview, instructions for using the video conferencing application and information about informed consent (written at an 8th grade reading level). If the video conferencing application fails to work properly, the recruiter will use this script to cancel the interview. *Script: Unfortunately, we cannot move forward if your [video conference application/Zoom] is not working properly because these interviews will be conducted over video chat. I'm sorry, we have to cancel this interview. Would it be okay if I added your name, telephone number, age, educational level, and race to our database so that I can contact you about other studies coming up in the future? Your information will be kept for up to 5 years and you can decide at any time to be removed from our database. Email recruitmentteam@cdc.gov to request removal. If yes, add to database. If no: OK, thank you for your time. Your name and any information you gave me will not be added to our database.*

Interview Procedure: Interviews will be conducted by CCQDER staff members and Research Support Solutions (RSS) contractors with English speaking respondents for up to 60 minutes per interview. Interviews are anticipated to be conducted virtually through the Zoom video conferencing application but may be conducted in-person in the QDRL or off-site.

In-person: After respondents have been briefed on the purpose of the study and the procedures that CCQDER routinely takes to protect human subjects, respondents will be asked to read and sign an Informed Consent document (Attachment 12). Respondents will also be asked to fill in their demographic characteristics on the Respondent Data Collection Sheet (Attachment 6).

Virtual: For virtual cognitive interviews, respondents and interviewers will see and hear each other through the video conference software from their own computer, tablet, or cellphone from their respective locations. A recruiter will meet the respondent on the scheduled video conferencing appointment (through Zoom). The recruiter will make sure the respondent is prepared for the interview and that the video conferencing application is working properly. The recruiter will go over the informed consent information that was previously emailed to the

respondent (Attachment 12) and remind the respondent of the remuneration procedure. If the application fails to work properly, the recruiter will use this script to cancel the interview.
Script: Unfortunately, we cannot move forward if your [video conference application/Zoom] is not working properly because these interviews will be conducted over video chat. I'm sorry, we must cancel this interview. Would it be okay if I added your name, telephone number, age, educational level, and race to our database so that I can contact you about other studies coming up in the future. Your information will be kept for up to 5 years and you can decide at any time to be removed from our database. Email recruitmentteam@cdc.gov to request removal. If yes, add to database. If no: OK, thank you for your time. Your name and any information you gave me will not be added to our database.

Once the videoconferencing software is working properly, the recruiter will collect the information from the Respondent Data Collection Sheet (Attachment 6). At this point, the interviewer will join the video conference, and the recruiter will leave the meeting.

The interviewer will then ask the respondent to confirm that he/she understands the information in the Informed Consent (Attachment 12), and then state that we would like to record the interview. The recorder will be turned on once it is clear that the procedures are understood and agreed upon.

Once the recording has started, the interviewer will confirm that the respondent has agreed to be recorded. The interviewer will confirm that the respondent has agreed to be recorded by asking, *"Do you agree that the interview will be video recorded? Yes, I agree or no, I don't agree."*

The interviewer will then orient the respondent to the cognitive interview with the following introduction:

[fill staff name] may have told you that we will be working on some questions that will eventually be added to national surveys. Before that happens, we like to test them out on a variety of people. The questions we are testing today are about diabetes and GLP-1 RA injectable medications]. We are interested in your answers, but also in how you go about making them. I may also ask you questions about the questions—whether they make sense, what you think about when you hear certain words, and so on.

*I will read each question to you, and I'd like you to answer as best you can. Please try to tell me what you are thinking as you figure out how to answer. Also, please tell me if:
there are words you don't understand,
the question doesn't make sense to you,
you could interpret it more than one way,
it seems out of order,
or if the answer you are looking for is not provided.*

The more you can tell us, the more useful it will be to us as we try to develop

better questions. Okay? Do you have any questions before we start? If yes, answer questions. If not, let's get started.

Video/Audio Recording: Video or audio recording is required for this project. These recordings will allow researchers to review the behaviors and body language of the respondents and to ensure the quality of their interview notes. Recordings will be used and retained in accordance with the CCQDER Data Storage and Access Policy (Attachment 8). Researchers from CCQDER and RSS contractors will use the recordings for research purposes. RSS contractors, NCCDPHP/DDT and NCHS researchers viewing/listening to recordings in the QDRL will be under CCQDER supervision have read and signed a non-disclosure affidavit (Attachment 9) and completed confidentiality training.

In-person: All interviews conducted in the QDRL or off-site will be video and/or audio recorded. In rare cases, a study participant may initially agree to be video recorded during the telephone screening but change their mind at the time of the interview. If the respondent changes their mind in the case of an in-person interview, the participant will be asked if they agree to be audio recorded. If they decline to be audio recorded the interview will proceed without recording. In these rare cases the requirement for audio recording will be relaxed and the interviewer will depend on their handwritten notes when conducting analysis.

Virtual: CCQDER will request permission to video record all virtual interviews conducted via Zoom. If the respondent consents to being video recorded and then changes their mind after the interview has begun, the interview will proceed with audio-only recording. In this case, the interviewer will instruct the respondent to turn off their camera and explain that only audio will be recorded as long as the respondent's camera remains off. In the event that the respondent's camera is turned back on, the interviewer will remind the respondent to turn the camera off if they do not want to be recorded. If the respondent does not want to be recorded but is unable to turn their camera off, the interview will be terminated.

NCHS government issued encrypted laptops will be used to video and audio record the interviews conducted off-site or virtually by both CCQDER researchers and RSS contractors. Interviewers can then securely upload their interview into **CDC's Secure Access Management Services (SAMS)** which has been approved by the ISSO **to securely exchange electronic files containing confidential information**. Interviews can then be downloaded by the SAMS/Q-Video Administrator onto an encrypted flash drive and then transferred to the CCQDER LAN. The recordings will then be deleted from SAMS. Alternatively, interviewers can use their NCHS government issued encrypted flash drive to transfer the recordings from the interviewer's laptop to the CCQDER's secure LAN. The encrypted flash drive is FIPS 140-2 compliant and approved for use by OCISO.

Extreme care will be taken with all recordings and paperwork from in person interviews conducted off-site. Identifying paperwork will be stored in a secured travel case until returned to NCHS, at which point the identifying paperwork will be transferred to the usual secured locked storage cabinets. Once the video and audio recordings are transferred to the secure QDRL Network (Q-Video), the recording will be deleted from SAMS.

After the interview: The recruiter will send the respondent a "thank you" email, informing them

that they will receive a hard copy “thank you” letter (Attachment 13) and their remuneration amount (\$50) in cash via FedEx within 7 business days. If electronic gift cards are used for remuneration, the respondent will be emailed the activation code for the gift card and an electronic copy of the “thank you” letter (Attachment 13).

Deletion of information: Once the interview is complete and the remuneration has been sent, all email, phone call and calendar records for the respondent will be deleted.

Retention of Recordings: The NCHS CCQDER Data Storage and Access policy (Attachment 8) governs retention of interviews, their viewing audience, the data kept, and the length of time before retention of interviews is reassessed. The data retention period for recordings of interviews that do not have consent for future use is until the completion of the project (upon completion of a final product or final sponsor briefing). Upon project completion, these non-retained recordings will be destroyed by designated CCQDER staff.

If a respondent requests that their recording be destroyed at the end of the project (virtual), the recording will be destroyed at the end of the project which is defined as when a report has been cleared by NCHS and submitted to Q-Bank. If the respondent gives future consent, 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 5 years.

Interview Notes: CCQDER staff and RSS contractors will also use the NCHS government issued encrypted laptops to input their interviewer notes into Q-Notes.

9. Explanation of Any Payment or Gift to Respondents

Focus Groups: For in person focus group participants will be given the standard remuneration of \$100 previously approved by OMB at the end of the focus group. Virtual focus group participants will be emailed the link and activation code for an \$100 electronic gift card as remuneration.

Cognitive Interviews: Cognitive interviewing respondents will be given the standard remuneration of \$50 approved by OMB on January 31, 2023, for CCQDER Generic data collection. For in person interviews, participants will be given \$50 in cash at the end of the interview. For virtual interviews, respondents will be emailed the link and activation code for an \$50 electronic gift card or (if cash is used) sent \$50 in cash via FedEx within 7 business days for remuneration.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

Data will be kept private to the extent allowed by law.

The CCQDER continues to collect, on a confidential basis, data needed in order to conduct CCQDER studies. Confidentiality provided to respondents is assured by adherence to Section 308(d) of the Public Health Service Act (42 U.S.C. 242m) which states:

“No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under section...306 (NCHS legislation),...may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose and (1) in the case of information obtained in the course of health statistical or epidemiological activities under section...306, such information may not be published or released in other form if the particular establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented (as determined under regulations of the Secretary) to its publication or release in other form...”

In addition, legislation covering confidentiality is provided according to the Confidential Information Protection and Statistical Efficiency Act or CIPSEA (44 U.S.C. 3561-3583), which states:

“Whoever, being an officer, employee, or agent of an agency acquiring information for exclusively statistical purposes, having taken and subscribed the oath of office, or having sworn to observe the limitations imposed by this section, comes into possession of such information by reason of his or her being an officer, employee, or agent and, knowing that the disclosure of the specific information is prohibited under the provisions of this subchapter, willfully discloses the information in any manner to a person or agency not entitled to receive it, shall be guilty of a class E felony and imprisoned for not more than 5 years, or fined not more than \$250,000, or both.”

Confidentiality of responses and safeguarding of data at NCHS

The CCQDER has a routine set of administrative, technical, and physical measures to safeguard confidentiality. Specific protocol for storage of confidential data, QDRL Lab, Q-video, Q-Notes, and Q-Bank access is described in CCQDER’s generic clearance package. (OMB No. 0920-0222, exp. 01/31/2026)

Records Retention Schedule for Cognitive Interviews

Storage and retention of CCQDER data is guided by the CCQDER Data Storage and Access Policy which governs retention of interviews, their viewing audience, the data kept, and the length of time before retention of interviews is reassessed. The Data Storage and Access Policy has been approved by the NCHS ERB and is included in CCQDER’s generic OMB package. In accordance with this policy, data from the current project will be re-evaluated by the CCQDER Director to determine relevance, ongoing usefulness and qualitative value for likely use in question evaluation research after an initial retention period of 5 years. The information of

individuals who did not qualify for the study and opt into our respondent database will be kept for 5 years. Removal from our database can be requested by emailing recruitmentteam@cdc.gov.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

NCHS and CDC Institutional Review Board (IRB) approved this data collection on October 1, 2024.

12. Estimates of Annualized Burden hours and costs

In January 2023, OMB approved 71,925 total number of respondents and 21,450 total burden hours. This GenIC NCHS is requesting 48 focus group respondents and 60 cognitive interviewing respondents totaling 144.48 burden hours.

Table 1: Burden table for NHIS Diabetes Focus Group and Cognitive Testing Project:

Form Name	Number of Participants	Number of Responses/Participants	Average hours per response	Response Burden (in hours)
Focus Group	48	1	85/60	68
Respondent Data Collection Sheets (Focus groups)	48	1	5/60	4
Screeners (all recruitment methods as described above (Attachment 3))	70	1	5/60	5.83
Screeners (all recruitment methods as described above (Attachment 11))	80	1	5/60	6.66
Questionnaire (Cognitive interviews)	60	1	55/60	55
Respondent Data Collection Sheets (Cognitive	60	1	5/60	5

interviews)				
Total				144.49