Supporting Statement A for Request for Clearance:

# COLLABORATING CENTER FOR QUESTIONNAIRE DESIGN AND EVALUATION RESEARCH

## Evaluation of Revised Questions on Cannabis Use and Experiences

OMB No. 0920-0222

Expiration Date: 01/31/2026

Contact Information:

Amanda Titus
Behavioral Scientist, Collaborating Center for Questionnaire Design and Evaluation Research
Division of Research and Methodology
National Center for Health Statistics/CDC
3311 Toledo Road, Room 5451
Hyattsville, MD 20782
301-458-4579
atitus@cdc.gov

1/30/24

## Table of Contents



LIST OF ATTACHMENTS

**Supporting Statement A**

**Collaborating Center for Questionnaire Design and Evaluation Research**

The staff of the National Center for Health Statistics (NCHS), Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) (OMB No. 0920-0222, exp. 01/31/2026) proposes to conduct a cognitive interviewing study to evaluate questions on cannabis use and experiences. Recruitment of respondents and interviewing would begin as soon as approval is received.

## A. JUSTIFICATION

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

As of August 2023, 52 U.S. states, districts, and territories, allow for some form of legalized cannabis use. Of these, 26 allow for nonmedical adult use of high-tetrahydrocannabinol (THC) cannabis, or "marijuana," without restrictions; 17 allow for adult medical use of marijuana; and 9 permit only the use of low-THC cannabidiol (CBD) products. Since NCHS/CCQDER's last evaluation of cannabis-related questions, the legal and regulatory environment has continued to develop, with several states enacting nonmedical adult use programs for the first time.[1] The changing landscape of cannabis legislation and cannabis use among the American population has produced large surveillance gaps. To address these, the National Center for Injury Prevention and Control (NCIPC), Division of Overdose Prevention (DOP) is proposing the cognitive evaluation of 17 questions on cannabis use and experiences that can be added to surveys of various populations. This study will assess the performance of these items in the general adult population. The items are intended to differentiate between non-psychoactive and psychoactive cannabis use and to understand:

- Modes of cannabis use
- The use of cannabis alongside and as a replacement for other substances
- Cannabis-impaired driving
- Physician-patient interactions related to cannabis
- Cannabis-related advertising
- The effect of changing laws on cannabis use

This study evaluates revised questions drawing on findings from the CCQDER's initial evaluation of cannabis-related questions in 2021 and 2022. That study aimed to understand how cannabis-related items function among the sub-population of adult cannabis product users, identify appropriate terminology to route survey respondents to questions germane to their experiences, and to understand whether questions function differently in various regulatory jurisdictions. The study concluded that respondents did not consistently understand the terms

1 Overview of Procedures for Cognitive Testing and Analyses of "Cannabis" Questions, NCHS ERB Protocol 2016-16-59.

"hemp or CBD-only products" and "marijuana," and changes to the cannabis product marketplace impacted this variation in question interpretation. On the other hand, a respondent's legal jurisdiction did not impact their understandings of questions and response options.

At NCIPC/DOP's request, the CCQDER recommended revisions to several items and to the structure of the instrument; these questions will be evaluated in the present study. The present study has three goals: to understand whether revisions to the questions and the instrument better distinguish between non-psychoactive and psychoactive forms of cannabis, to examine the extent to which proposed revisions reduce or eliminate response error, and to understand the functioning of these items among the adult population that does not use any cannabis products.

The questions to be evaluated were derived from several sources. The questions to be tested are included as Attachment 1.

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

NCHS' Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) conducts question evaluation studies, for both applied and methodological purposes, with particular focus on question design, measurement, comparability, and error.

The purpose and use of collecting this information is for the:

> Development and testing of specific survey items on cannabis use and experiences for the National Center for Injury Prevention and Control (NCIPC), Division of Overdose Prevention (DOP), Cannabis Strategy Unit (CSU).

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

The CCQDER continues to collect, on a confidential basis, data needed in order to conduct CCQDER studies. The process of informing respondents of the procedures used to keep information confidential begins with the telephone screener and will carry through to the interviewer and all communications with potential respondents. Materials will include all elements of informed consent, including the purpose of the data collection, the voluntary nature of the study, audio recording of the interview, and the effect upon the respondent for terminating the interview at any time.

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."

The CIPSEA legislation authorizes the designation of agents ("designated agents" or "agents") to perform statistical activities on behalf of an agency. These agents function under the supervision of the agency's employees and are subject to the same provisions of law with regard to confidentiality as an agency's employees. A Designated Agent Agreement between the agency and the designated agents (e.g. contractors) must be executed before the agents can acquire information for the agency for exclusively statistical purposes under a pledge of confidentiality. This requirement is outlined in an OMB Notice, published in the Federal Register on June 15, 2007, entitled "Implementation Guidance for Title V of the E-Government Act, Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA)."

A Designated Agent Agreement between NCHS and any CCQDER contractor will be executed if any contractors are hired to acquire information for the NCHS for exclusively statistical purposes under a pledge of confidentiality (i.e. complete any of the five types of activities described in this generic clearance request). Additionally, the agents (contractors) will be required to complete NCHS Confidentiality Training (https://www.cdc.gov/nchs/training/confidentiality/training/), submit a certificate of completion, and sign a pledge to maintain confidentiality (Nondisclosure Affidavit; see Attachment 9) prior to completing CCQDER work. If the CCQDER contractor hires subcontractors to complete CCQDER work, the subcontractors must adhere to the same confidentiality and security requirements as CCQDER staff and contractors.

Data in identifiable form are collected for linkage of various CCQDER forms (informed consent documentation and respondent demographics) and audio recordings. The CCQDER also uses some identifiable data (name, phone number, email address) to contact previous respondents for CCQDER studies. The ability to match respondents to other data (informed consent documents, respondent demographics, and audio recordings) greatly expands the usefulness of the data at a very low cost.

As outlined in the informed consent form, access to personal information is restricted to CCQDER staff who can only access the personal information for statistical, training and research purposes. Additionally, other NCHS staff, designated agents such as CCQDER contractors, or subcontractors may access the personal information for statistical purposes only after signing a Designated Agent Agreement with NCHS. CCQDER staff, designated agents, and staff from collaborating agencies must complete annual NCHS confidentiality training (https://www.cdc.gov/nchs/training/confidentiality/training/), submit a certificate of completion, and sign the NCHS affidavit of nondisclosure (see Attachment 9) prior to being granted access to any personal information.

The collection of information in identifiable form requires strong measures to ensure that private information is not disclosed in a breach of confidentiality. Storage of confidential data is protected through procedures such as an internal QDRL LAN, passwords and restricted access.

**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**

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 2 years.

*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 7) 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 7).

*Deletion of information:*

Once the interview and follow-up call (if conducted) are complete and the remuneration has been sent, all email, phone call and calendar records for the respondent will be deleted.

*Interview Notes:*

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

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

NCHS Ethics Review Board (ERB) and the CDC Institutional Review Board approved this data collection on 11/27/2023.

### Informed Consent and Voluntary Nature

**CCQDER respondents/interviews conducted at NCHS**

Respondents are recruited through media advertisements, flyers, and word-of-mouth, and either call the CCQDER voice mail system or contact a person coordinating the recruitment. Data collection for this project is authorized under 42 U.S.C. 242k (Section 306 of the Public Health Service Act).

During the telephone screener (Attachment 4), potential respondents are informed that answering the telephone screener questions to determine their eligibility for the study is completely voluntary. They are informed that we are required by law to use the information they provided in the telephone screener for statistical research only and to keep it confidential, and that the law prohibits us from giving anyone any information that may identify them without their consent. In addition, respondents who are determined to be eligible for the study are informed during the telephone screener that the information they provide during the cognitive interview is confidential.

Prior to the start of the cognitive interview, CCQDER respondents read and sign Attachment 5, Informed Consent Form (written at an 8$^{th}$ grade reading level). The consent form states that participation is voluntary, they are free to terminate the interview at any time, and if they do so, they will still receive the incentive. The consent form describes the purpose of the interview and recording, specifies that the recordings may be played for other staff working closely on that project, that voice and face identifiers will remain on the recording, and that they may be recognized by a staff member viewing or listening to the recording. Cognitive interviews deemed to be about illegal behaviors will not be video recorded, only audio recorded. Respondents are given a copy of the consent form, which contains contact information for the CCQDER Laboratory Manager, the NCHS Research Ethics Review Board (ERB), and the NCHS Confidentiality Officer.

**CCQDER respondents/interviews conducted off-site**[2]: Sometimes interviewers must travel to conduct cognitive interviews in these cases, a mutually agreeable location will be chosen. In all cases, extreme care is taken with audio recordings and any materials that contain personal identifiers such as the Informed Consent Form or the Special Consent for Expanded Use of Audio Recordings Materials are then transported to the CCQDER, where standard procedures are followed.

**CCQDER respondents/interviews conducted virtually:** Respondents are recruited through media advertisements, flyers, and word-of-mouth, and either call the CCQDER voice mail system or contact a person coordinating the recruitment.

During the telephone screener (Attachment 4), potential respondents are informed that answering the telephone screener questions to determine their eligibility for the study is completely voluntary. They are informed that we are required by law to use the information they provided in the telephone screener for statistical research only and to keep it confidential, and that the law prohibits us from giving anyone any information that may identify them without their consent. In addition, respondents who are determined to be eligible for the study are informed during the telephone screener that the information they provide during the cognitive interview is confidential.

Prior to the start of the cognitive interview, CCQDER respondents read and sign Attachment 5. The consent form states that participation is voluntary, they are free to terminate the interview at any time, and if they do so, they will still receive the incentive. The consent form describes the purpose of the interview and recording, specifies that the recordings may be played for other staff working closely on that project, that voice and face identifiers will remain on the recording, and that they may be recognized by a staff member viewing or listening to the recording. After the interview has concluded respondents will be given the thank-you letter signed by Director of NCHS (Attachment 7), their incentive, and a copy of the informed consent document (Attachment 5), which contains contact information for the CCQDER Laboratory Manager, the NCHS Research Ethics Review Board (ERB), and the NCHS Confidentiality Officer.

NCHS government issued encrypted laptops will be used to 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

---

2

Off-site interviews fall into two categories. First, it is not always feasible for individuals to travel to the CCQDER, or it may be more efficient for interviewers to travel to a particular site. Second, we occasionally conduct establishment studies where a visit to the business location is pertinent to data collection.

to the CCQDER's secure LAN. The encrypted flash drive is FIPS 140-2 compliant and approved for use by OCISO.

Procedure for Sending Interview recording via SAMS and Uploading into Q-Video

1. All audio recordings of off-site and virtual interviews will be saved to NCHS government issued encrypted laptops
2. Immediately after the interview, the researcher will upload the saved file into the CDC SAMS environment (Secure Access Management Service (cdc.gov))
3. The researcher will immediately delete the file from their NCHS government issued encrypted laptop
4. After the cognitive interview files 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 cognitive interview 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.

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

Extreme care will be taken with all recordings and paperwork from the interviews conducted virtually. 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. Once the audio recordings are transferred to the QDRL Network, the recordings will be deleted from encrypted flash drive. Once deleted, the files are no longer available for use.

**Contractor conducted interviews**

Sometimes contractors (designated agents) are used to collect data as part of CCQDER projects, they are contractually bound by NCHS confidentiality provisions and must submit documentation concerning their safeguarding practices to NCHS prior to data collection. The documentation is reviewed by the NCHS Confidentiality Officer and the NCHS Information Systems Security Officer. This is standard NCHS practice and does not reflect a special CCQDER procedure. If recordings are to be shared with the contractor, a contract as well as a Designated Agent Agreement will be developed. The contractor employee will view the NCHS confidentiality training (https://www.cdc.gov/nchs/training/confidentiality/training/), submit a

certificate of completion, and sign the NCHS non-disclosure statement (see Attachment 9) before starting work on the project.

**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. For this GenIC NCHS is requesting 100 respondents and 58.

Burden table for Cannabis Use and Experiences:

| **Form Name** | **Number of Participants** | **Number of Responses/Participants** | **Average hours per response** | **Response Burden (in hours)** |
|---|---|---|---|---|
| Screener (all recruitment methods as described above (Attachment 4) | 100 | 1 | 5/60 | 8 |
| Questionnaire | 50 | 1 | 55/60 | 46 |
| Respondent Data Collection Sheets | 50 | 1 | 5/60 | 4 |
| Total | | | | 58 |