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

RANDS 11

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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

The staff of the National Center for Health Statistics' (NCHS) Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) in the Division of Research and Methodology (DRM) is requesting NCHS Office of Science and the CDC Institutional Review Board approval to evaluate several general health-related topics as part of NCHS' Research and Development Survey (RANDS) Program, in collaboration with the staff of the National Center for Injury Prevention and Control (NCIPC) and National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP). As with most of the rounds of RANDS that have been approved in the past, the survey content for this round will be related to health and will generally mirror content found on the National Health Interview Survey (NHIS), the National Health and Nutrition Examination Survey (NHANES), the Household Pulse Survey, and the Behavioral Risk Factor Surveillance System (BRFSS). The overall goals of this round of RANDS will be to evaluate potential questions for NCHS surveys and to continue to develop NCHS' statistical and weighting approaches to using commercial survey panel data.

The methodological survey will follow the same protocols approved for previous rounds of CCQDER RANDS projects and will use NORC's AmeriSpeak Panel as its sample source. As is

typical for RANDS projects, the data will be used by NCHS for methodological purposes only, and public data files will be released along with extensive documentation about the limitations of the data.

We propose to start programming the survey instrument for the methodological survey as soon as we receive OMB clearance.

Proposed Project: RANDS 11

As the nation's principal health statistics agency, NCHS is responsible for producing high-quality statistics on the health and wellbeing of the American public and the state of the country's health care system, as well as contributing to the development of survey methodologies that will allow the agency to continue producing these health statistics in the future. As the NCHS ERB and the CDC IRB have previously approved in prior RANDS submissions, NCHS uses commercially available, pre-existing survey panels to supplement its ongoing examinations of measurement error and estimation techniques. This methodological survey system—NCHS' RANDS—has allowed the Center to conduct meaningful subgroup analyses of survey response patterns, explore patterns of survey item interpretation and potential reporting errors at a population level, and provides an opportunity to explore how estimates from commercial survey panels might be used in the future to supplement NCHS' official statistics information collections and survey systems.

The questionnaire proposed for RANDS 11 is in Attachment 1. In addition to the inclusion of the standard RANDS variables that allow NCHS to calibrate RANDS to the NHIS, this questionnaire covers other topics that will help NCHS, NCIPC, and NCCDPHP advance their methodological research, including:

- Cannabis use and experiences: The legal and regulatory environment around cannabis possession, cultivation, and use is rapidly changing. As of August 2024, 50 U.S. states, districts, and territories allow for some form of legalized cannabis use. Of these, 25 allow for nonmedical adult use of high-tetrahydrocannabinol (THC) cannabis, or "marijuana," without restrictions; 14 allow for adult medical use of marijuana; and 11 permit only the use of low- or no-THC cannabidiol (CBD) products. The varied and dynamic legal landscape and changing patterns of cannabis use among the American public have produced large public health surveillance gaps. NCHS/CCQDER has conducted two rounds of cognitive evaluation of various items on cannabis use and experiences intended to be added to surveys of various adult populations. This round of RANDS includes various items intended to differentiate between non-psychoactive and psychoactive cannabis use and covering a variety of topics, including modes of cannabis use, the use of cannabis alongside and as a replacement for other substances, cannabis-impaired driving, physician-patient interactions, and cannabis-related advertising. Items included on RANDS 11 reflect the results of both rounds of CCQDER's qualitative question evaluation.
- Cognitive decline: Recognizing the importance of cognitive decline as a public health issue, the NCCDPHP Alzheimer's Disease and Healthy Aging Program, in collaboration with national experts, developed and implemented an optional module of questions on self-assessed cognitive decline, for states to use on the Behavioral

Risk Factor Surveillance System (BRFSS)¹. Due to the revisions, CDC's Alzheimer's Disease Science Team anticipates that the prevalence of subjective cognitive decline and other measures will change. A quantitative split sample experiment conducted during 2022-2023 supports this assumption. This experiment showed notable differences in results between the original version of the module and the revised version, but without explanation. This round of RANDS includes seven items and two versions of an introduction to these items for use in a split-sample experiment, where half of the respondents receive each version of the introduction. Qualitative cognitive evaluation of these items has already received NCHS ERB and CDC IRB approval and will inform the precise design of web probes included in RANDS 11.

Whole Person Health: Following the analysis of RANDS 10 data, a series of items
measuring whole person health (WPH), proposed by the National Center for
Complementary and Integrative Health, will be administered in the 2025 NHIS.
RANDS 11 will continue this evaluation effort by integrating construct probes after
selected WPH items to determine the measurement properties of these novel
questions.

The previous use and development of these items is described in Attachment 2. NCHS understands that OMB approval for evaluation of these questions does not imply or guarantee future approval for use or application of these or similar items.

RANDS 11

Specific Plans for the Proposed Study: As with previous rounds of RANDS, DRM proposes that RANDS 11 function as a methodological study to provide a testbed for NCHS' estimation and question evaluation research. The design of RANDS 11 will conform to the survey techniques that have been described in CCQDER's generic clearance package (OMB No. 0920-0222, exp. 01/31/2026). Within that framework, the following procedures are particular to this study:

Sample: This round of RANDS will be administered by NORC at the University of Chicago (NORC) across both web and phone modes, according to panelist preference (approximately 10% of the AmeriSpeak panelists are "phone-only" respondents who only take surveys via a phone interviewer). We are requesting approval to obtain 8,600 complete responses from the AmeriSpeak panel, including 8,000 web responses and 600 phone responses for one round of data collection. Previous rounds of RANDS that have used both phone and web AmeriSpeak panel respondents have obtained sample completion rates averaging 72.5%. Additionally, we are requesting approval to obtain an additional 10,000 complete responses from an opt-in supplemental panel. As we have done in previous rounds of RANDS that incorporated an opt-in sample, NORC will work with an outside vendor to bring opt-in respondents into its own survey environment for the purpose of this single survey. While the data from opt-in samples is not of the same quality as that from the AmeriSpeak sample, including this supplementary sample will allow DRM to continue its investigations into combining various types and provenances of data, in an effort to develop and build out methodologies that will allow the Center to produce actionable public health data and findings on small-scale and hard-to-reach

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¹ CDC - BRFSS

subpopulations.

Survey Administration and Data Compilation: The proposed RANDS 11 will be conducted as soon as OMB clearances are granted. For one round, NORC anticipates a field period of approximately 1 month. As with previous rounds, the RANDS 11 survey will begin with an introduction screen (or introduction text for telephone respondents) like what is seen at the beginning of Attachment 2, explaining the general purpose of the survey and providing the consent, confidentiality, and Paperwork Reduction Act language. As signed consent is not possible for internet surveys where the population of respondents is anonymous to NCHS, as in a commercial panel, we request a waiver of signed consent from the CDC IRB (as has been the case in all **previous rounds of RANDS)**. The introduction page will require the respondent to manually click through to the first page of questions (or agree to continue and not hang up for telephone respondents); this action therefore implies consent. As with all previously approved rounds of RANDS that used NORC's AmeriSpeak panel, NCHS will not provide an incentive to panelists participating in RANDS, though NORC does provide non-cash incentives in the form of "AmeriPoints" that panelists can accumulate and exchange for items such as gift cards. We anticipate it will take a respondent an average of 20 minutes to complete the web or phone interview.

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."

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 (Attachment 3) 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.

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 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).

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

NCHS and CDC Institutional Review Board (IRB) approved this data collection on 10/22/2024.

12. Estimates of Annualized Burden hours and costs (Table 1 was approved by OMB on January 31, 2023, for CCQDER's Generic data collection, OMB No. 0920-0222)

In January 2023, OMB approved 71,925 total number of respondents and 21,450 total burden hours. This GenIC NCHS is requesting 18,600 respondents and 6,200 burden hours.

Burden table for RANDS 11:

Form Name	Number of Participants	Number of Responses/Participants	Average hours per response	Response Burden (in hours)
Methodological	18,600	1	20/60	6,200
Survey				
Total				6,200