

*Background and Brief Description*

The National Center for Health Statistics (NCHS) has submitted a six-month OMB emergency clearance for a Research and Development Survey (RANDS) COVID-19 related data collection. Since COVID-19 has resulted in a public health crisis, this information collection requests approval to conduct a follow-on survey (Round 3) to the previously completed rounds of RANDS. Similar to the previous two rounds of RANDS completed during COVID-19, this information collection

will use NORC’s AmeriSpeak Panel as its sample source.

The RANDS COVID-19 (Round 3) collection will be used for the purpose of continuing NCHS’ developmental survey methods and will generate data that can help explain health-related experiences of the United States population during this period. The data collection includes not only a research component, but will also contribute to CDC’s ongoing surveillance of the COVID-19 pandemic. Given the current outbreak and the resulting limitations placed on NCHS’ other data collections,

RANDS will provide NCHS and CDC with early estimates of COVID-19-related concepts. The questionnaire will cover areas such as general health, psychological distress, chronic conditions, health behaviors, the outbreak’s effects on healthcare access, loss of work due to illness with COVID-19, telemedicine access and use, and other health and behavioral aspects related to the epidemic. CDC requests approval for an estimated 1,734 burden hours over the course of the six-month approval. There are no costs to respondents other than their time.

**ESTIMATED ANNUALIZED BURDEN TABLE**

Types of respondents	Form name	Number of participants	Number of responses/participant	Average hours per response	Response burden (in hours)
Individuals or households .....	RANDS-COVID-19 Round 3 .....	5,200	1	20/60	1,734
Total .....	.....	5,200	.....	.....	1,734

**Jeffrey M. Zirger,**

*Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60Day-21-0840 Docket No. CDC-2021-0010]

**Proposed Data Collection Submitted for Public Comment and Recommendations**

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled “NCHHSTP Generic Clearance Formative Research and Tool Development”. This information collection request is designed to allow CDC’s National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

(NCHHSTP) to conduct formative research information collection activities used to inform many aspects of surveillance, communications, health promotion, and research project development for NCHHSTP’s four priority diseases (HIV/AIDS), sexually transmitted diseases/infections (STD/STI), viral hepatitis, tuberculosis elimination (TB), and school and adolescent health (DASH).

**DATES:** CDC must receive written comments on or before April 13, 2021.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2021-0010 by any of the following methods:

- *Federal eRulemaking Portal:* [Regulations.gov](https://www.regulations.gov). Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS-D74, Atlanta, Georgia 30329.

*Instructions:* All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to [Regulations.gov](https://www.regulations.gov).

*Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.*

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS-

D74, Atlanta, Georgia 30329; phone: 404-639-7118; Email: [omb@cdc.gov](mailto:omb@cdc.gov).

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated,

electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

**Proposed Project**

NCHHSTP Generic Clearance Formative Research and Tool Development (OMB Control No. 0920–0840, Exp. 10/31/2021)—Extension—National Center for HIV/AIDS, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

The Centers for Disease Control and Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) requests approval for an extension and a three year approval for the previously approved Generic Clearance, “Formative Research and Tool Development”. This information collection request is designed to allow NCHHSTP to conduct formative research information collection activities used to inform many aspects of surveillance, communications, health promotion, and research project development for NCHHSTP’s four priority diseases (HIV/AIDS, sexually transmitted diseases/infections (STD/STI), viral hepatitis, tuberculosis elimination and the Division of School and Adolescent Health (DASH). Formative research is the basis for developing effective strategies including communication channels, for influencing behavior change. It helps researchers identify and understand the characteristics—interests, behaviors and needs—of target populations that influence their decisions and actions.

Formative research is integral in developing programs as well as improving existing and ongoing programs. Formative research also looks at the community in which a public health intervention is being or will be implemented and helps the project staff understand the interests, attributes and

needs of different populations and persons in that community. Formative research is research that occurs before a program is designed and implemented, or while a program is being conducted. NCHHSTP formative research is necessary for developing new programs or adapting programs that deal with the complexity of behaviors, social context, cultural identities, and health care that underlie the epidemiology of HIV/AIDS, viral hepatitis, STDs, and TB in the U.S., as well as for school and adolescent health.

CDC conducts formative research to develop public-sensitive communication messages and user friendly tools prior to developing or recommending interventions, or care. Sometimes these studies are entirely behavioral but most often they are cycles of interviews and focus groups designed to inform the development of a product. Products from these formative research studies will be used for prevention of HIV/AIDS, Sexually Transmitted Infections (STI), viral Hepatitis, and Tuberculosis. Findings from these studies may also be presented as evidence to disease-specific National Advisory Committees, to support revisions to recommended prevention and intervention methods, as well as new recommendations.

Much of CDC’s health communication takes place within campaigns that have lengthy planning periods—timeframes that accommodate the standard Federal process for approving data collections. Short term qualitative interviewing and cognitive research techniques have previously proven invaluable in the development of scientifically valid and population-appropriate methods, interventions, and instruments.

This request includes studies investigating the utility and acceptability of proposed sampling and recruitment methods, intervention contents and delivery, questionnaire domains, individual questions, and interactions with project staff or electronic data collection equipment. These activities will also provide information about how respondents

answer questions and ways in which question response bias and error can be reduced.

This request also includes collection of information from public health programs to assess needs related to initiation of a new program activity or expansion or changes in scope or implementation of existing program activities to adapt them to current needs. The information collected will be used to advise programs and provide capacity-building assistance tailored to identified needs. Overall, these development activities are intended to provide information that will increase the success of the surveillance or research projects through increasing response rates and decreasing response error, thereby decreasing future data collection burden to the public. The studies that will be covered under this request will include one or more of the following investigational modalities: (1) Structured and qualitative interviewing for surveillance, research, interventions and material development, (2) cognitive interviewing for development of specific data collection instruments, (3) methodological research (4) usability testing of technology-based instruments and materials, (5) field testing of new methodologies and materials, (6) investigation of mental models for health decision-making, to inform health communication messages, and (7) organizational needs assessments to support development of capacity.

Respondents who will participate in individual and group interviews (qualitative, cognitive, and computer assisted development activities) are selected purposively from those who respond to recruitment advertisements. In addition to utilizing advertisements for recruitment, respondents who will participate in research on survey methods may be selected purposively or systematically from within an ongoing surveillance or research project. Participation by respondents is voluntary. There is no cost to participants other than their time.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average hours per response	Total response burden (hours)
General public and health care providers.	Screener .....	81,200	1	10/60	13,533
General public and health care providers.	Consent Forms .....	40,600	1	5/60	3,383
General public and health care providers.	Individual Interview .....	6,600	1	1	6,600
General public and health care providers.	Focus Group Interview .....	4,000	1	2	8,000

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average hours per response	Total response burden (hours)
General public and health care providers.	Survey of Individual .....	30,000	1	30/60	15,000
Total .....	.....	.....	.....	.....	46,516

**Jeffrey M. Zirger,**

*Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[Document Identifiers CMS-10518 and CMS-10340]

**Agency Information Collection Activities: Proposed Collection; Comment Request**

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS’ intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency’s functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by April 13, 2021.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and

recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for “Comment or Submission” or “More Search Options” to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number \_\_\_\_\_, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS’ website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

**FOR FURTHER INFORMATION CONTACT:** William N. Parham at (410) 786-4669.

**SUPPLEMENTARY INFORMATION:**

**Contents**

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection’s supporting statement and associated materials (see **ADDRESSES**).

CMS-10518 Application for Participation in the Intravenous Immune Globulin (IVIG) Demonstration

CMS-10340 Collection of Encounter Data from MA Organizations

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or

provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

**Information Collection**

1. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Application for Participation in the Intravenous Immune Globulin (IVIG) Demonstration; *Use:* Traditional fee-for-service (FFS) Medicare covers some or all components of home infusion services depending on the circumstances. By special statutory provision, Medicare Part B covers intravenous immune globulin (IVIG) for persons with primary immune deficiency disease (PIDD) who wish to receive the drug at home. However, Medicare does not separately pay for any services or supplies to administer it if the person is not homebound and otherwise receiving services under a Medicare Home Health episode of care. As a result, many beneficiaries have chosen to receive the drug at their doctor’s office or in an outpatient hospital setting.

The Medicare IVIG Demonstration application requests basic demographic information necessary to determine eligibility for participation in the demonstration. This information is used by CMS’ implementation support contractor to determine eligibility for the demonstration and to set up a demonstration eligibility record that is used by the Medicare claims system when processing claims for demonstration services.

The application also includes some questions about how and where the beneficiary is currently receiving immunoglobulin and related services. This data is being used by the evaluation contractor to conduct its evaluation and to better understand