Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Researchers	ALS Biorepository Saliva Collection	350	1	10/60	58
	ALS Registry Research Application Form	36	1	30/60	18
	Annual Update	24	1	15/60	6
ALS Service Organizations.	Chapter/District Outreach Reporting Form	135	12	5/60	135
	National Office Outreach Reporting Form	2	12	20/60	8
Total					1,757

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, 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

[30Day–25–1357]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''The Greater Access and Impact with NAT (GAIN) Study: Improving HIV Diagnosis, Linkage to Care, and Prevention Services with HIV Point-of-Care Nucleic Acid Tests (NATs)'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on January 8, 2025, to obtain comments from the public and affected agencies. CDC received no comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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 submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

The Greater Access and Impact with NAT (GAIN) Study: Improving HIV Diagnosis, Linkage to Care, and Prevention Services with HIV Point-of-Care Nucleic Acid Tests (NATs) (OMB Control No. 0920–1357)—Reinstatement—National Center for HIV, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC is requesting reapproval for three years of the data collection titled The Greater Access and Impact with NAT (GAIN) Study: Improving HIV Diagnosis, Linkage to Care, and Prevention Services with HIV Point-of-Care Nucleic Acid Tests (NATs). The purpose of this information collection is to determine the acceptability and feasibility of HIV point of care nucleic acid tests (POC NAT) for HIV in clinical and community settings. Current rapid POC technologies do not reliably detect the earliest HIV infections and lab-based testing can introduce delays while patients wait for test results. During this time, patients can drop out of care and are still at high-risk to become infected. POC NATs can identify early HIV infections, which have high potential for transmission. POC NATs have the potential to help address some of the remaining challenges to ending the HIV epidemic in the United States by assisting with early detection of acute HIV infection and by providing a more efficient viral load monitoring tool for people living with HIV. This study is the first of its kind in the U.S. and is critical to understanding the feasibility and acceptability of POC NAT use in the U.S.

Data collected during this study will be used to evaluate the performance of POC NAT and associated clinical outcomes, patient and provider perspectives regarding acceptability and feasibility, and implementation science outcomes. The GAIN study will develop, implement, and evaluate models for use of POC NAT among HIV-negative persons seeking HIV testing, PEP, and PrEP and HIV-positive persons in community and clinical settings.

Prior to study expiration in December 2024, the GAIN project was successful in meeting several information collection goals. GAIN is on track to reach remaining data collection targets and successfully conclude this important information collection if the study is reinstated. A limited number of data collection activities remain to be completed; therefore, the annual number of respondents needed to complete the study have been reduced from 3,494 to 150. Accordingly, the

annualized burden will also decrease from 880 to 49 hours. GAIN study stakeholders noted several opportunities to improve the participant experience and improve data quality by refining existing tools and collecting additional data; therefore, we propose the addition of three new study instruments and minor revisions to four study instruments.

The study will be carried out in Seattle, Washington at two locations: the Gay City community center and the Madison Clinic. Gay City is the largest community-based testing program in Washington. Madison Clinic is the largest provider of HIV care in the state. Upon reinstatement, GAIN will engage four types of participants: (1) persons living with HIV (PLWH) and receiving care at Madison Clinic; (2) individuals enrolled in GAIN at the community center prior to study expiration; (3) health providers at Madison Clinic; and (4) clinic staff from both study locations. All participants will be at least 18 years of age and able to read and speak English.

In order to complete our evaluation of the impact of POC NAT on time to virologic suppression among PLWH receiving antiretroviral therapy (ART), we will enroll 61 PLWH who are receiving ART at Madison Clinic. Participants will be recruited using a combination of approaches including in-person outreach, health provider referrals, and printed media (flyers) displayed in the clinic. Following screening and enrollment, a computer-assisted quantitative survey will collect participant demographics and information about substance use, pre-exposure prophylaxis (PrEP) use, and antiretroviral therapy (ART). Following the study visit, a web link to the online acceptability survey will be sent to them via email. The survey will collect information about participants' knowledge about their POC NAT results, their perception about the accuracy of those results, and their level of confidence in the results. The survey will also collect information about test result sharing, HIV treatment and test result knowledge and beliefs, ART adherence, and communications with their provider. A subset of the cohort will be randomly selected by study staff and invited to participate in a focus group or interview to further explore their experiences and preferences for HIV testing, and to evaluate their reactions to the intervention. Interviews and focus groups may be conducted in person or remotely via a secure, teleconference platform.

A subset of participants who were enrolled at Gay City will be randomly selected, contacted by study staff via telephone, and invited to participate in a brief survey. Depending on the group they were enrolled in, the survey will collect information to determine if the participant initiated PrEP, engaged in HIV care, or is successfully taking ART. Study staff may call a participant up to three times to discuss the outcome of their study visit. The five-minute survey will provide the information needed to evaluate the impact of POC NAT on the outcomes of respondents who participated in the GAIN study at the community center.

Health providers and clinic staff at Madison Clinic who referred patients to the GAIN study and saw patients enrolled in the study will be invited by study staff, either in person or via email, to participate in an interview to describe their experiences with POC NAT and preferences for HIV testing. Participants will have the option to attend the interview in-person or remotely via telephone or a teleconference platform. Providers will be invited to complete up to three interviews over the course of the study in order to capture the provider experience over time and in varying clinical scenarios. Clinic staff with expertise in electronic health record management will be engaged at each of the study sites to collect medical record data, including test dates and results.

Data will be collected from a total of 181 individuals over the three-year data collection period, including 61 PLWH receiving care at Madison Clinic; 18 health providers at Madison Clinic; 100 participants at the Gay City center; and two clinic employees. For PLWH participants, we estimate that we will need to screen 122 individuals (41 annually) to reach total enrollment. The screening process will take approximately five minutes to complete. Following enrollment, 61 participants (21 annually) will complete the Release of Information form which will take five minutes to complete. The study visit survey will take 15 minutes to complete and will be delivered to 61 participants (21 annually) once. A total of 61 participants (21 annually) will complete the acceptability survey which will take 20 minutes to complete. A subset of participants (12 total, four annually) will be invited to participate in a focus group or interview which may take up to one hour to complete. A follow-up telephone survey will be conducted with participants who were enrolled at Gay City (100 total, 34 annually). The survey will take five minutes to complete, and participants may be called up to three times. Health providers (18 total, six annually) at Madison Clinic will be invited to participate in up to three interviews which will take 45 minutes to complete. One clinic employee at each of the two study sites will be engaged to collect medical record data. The Madison Clinic will perform an automated data collection, estimated to take five minutes, once every two months (six times annually). Gay City center will perform a manual data pull, estimated to take one hour, once every six months.

CDC is requesting OMB approval for 135 total burden hours across three years of data collection. The total estimated annualized burden hours are 49. Participation of 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 burden per response (in hr)
General Public—Adults	Screen and Link	41	1	5/60
General Public—Adults	Release of Information	21	1	5/60
General Public—Adults	Study Visit Survey	21	1	15/60
General Public—Adults	Acceptability Survey	21	1	20/60
General Public—Adults	Participant Focus Group and Interview Guide	4	1	1
General Public—Adults	Follow Up Phone Call Survey	34	3	5/60
Health Practitioners	Provider Interview Guide	6	3	45/60
Health Practitioners	Madison Clinic Data Collection	1	6	5/60
Health Practitioners	Gay City Data Collection	1	2	1

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, 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

[30-Day–26–1317]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''National Healthcare Safety Network (NHSN) Respiratory Data'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on June 16, 2025 to obtain comments from the public and affected agencies. CDC received two comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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 submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

National Healthcare Safety Network (NHSN) Respiratory Data (OMB Control No. 0920–1317 Exp. 01/31/2028)—Revision—National Center for Emerging Zoonotic and Infections Disease (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Healthcare Quality Promotion (DHQP), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC) collects COVID–19 and respiratory virus data from healthcare facilities in the National Healthcare Safety Network (NHSN) under OMB Control Number 0920–1317. NHSN is the only national system that collects surveillance data on healthcare-associated infections, infection prevention process measures, healthcare personnel safety measures, such as blood and body fluid exposures and vaccination practices, and adverse events related to the transfusion of blood and blood products. The NHSN existing platform allows facilities to share data immediately with local, state, and national partners for impact monitoring, decision-making, and surveillance activities.

The NHSN Respiratory Data Modules are designed to standardize the data elements collected across the country regarding the impact of the COVID–19 and other respiratory viruses on healthcare facilities. In collecting standardized data, NHSN provides a vendor-neutral platform and a national lens into the burden hospitals are experiencing in a way that is designed to support the public health response. NHSN is a platform that exists in nearly all acute-care hospitals, nursing homes, and dialysis facilities in the US and can provide a secure, sturdy infrastructure.

The current Revision request is submitted to: (1) change the official name of the data collection; (2) make small changes to language and wording of NHSN questions; (3) modify questions to comply with Executive Orders; and (4) revise burden and cost estimates. CDC requests OMB approval for an estimated 1,725,736 annual burden hours. There are no costs to respondents other than their time to participate.

Estimated Annualized Burden Hours

Type of respondent	Form No.	Form	Number of respondents	Number of responses per respondent	Average burden per response
Microbiologist	57.101	Hospital Respiratory Data Form (Weekly) (user entry).	1148	52	202
Microbiologist	57.101	Hospital Respiratory Data Form (Weekly) (.csv import).	3444	52	29
Information Technology	57.101	Hospital Respiratory Data Form (Weekly) (API)	1786	52	15
Microbiologist	57.102	Hospital Respiratory Data Form (Daily) (user entry).	492	365	58
Microbiologist	57.102	Hospital Respiratory Data Form (Daily) (.csv import).	1476	365	29
Information Technology	57.102	Hospital Respiratory Data Form (Daily) (API)	765	365	15
Microbiologist	57.140	National Healthcare Safety Network (NHSN) Registration Form.	11500	1	5
Microbiologist	57.155	Point of Care Testing Results-Manual	3135	150	11
Microbiologist	57.155	Point of Care Testing Results-CSV	3135	150	11