



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[30Day-25-0573]

#### 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 HIV Surveillance System (NHSS)” 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 April 1, 2022 to obtain comments from the public and affected agencies. CDC received two comments related to the previous notice. No changes were made to the information collection plan. 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](http://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 HIV Surveillance System (NHSS) (OMB Control No 0920 – 0573, Exp, 02/28/2026) – Revision – National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

Collected with authorization under Sections 304 and 306 of the Public Health Service Act (42 U.S.C. 242b and 242k), the National HIV Surveillance System (NHSS) data are the primary data used to monitor the extent and characteristics of the HIV burden in the United States. HIV surveillance data are used to describe trends in HIV incidence, prevalence and characteristics of infected persons and used widely at the federal, state, and local levels for planning and evaluating prevention programs and healthcare services, to allocate funding for prevention and

care, and to monitor progress toward achieving national prevention goals of the Ending the HIV Epidemic in the U.S initiative.

The Division of HIV Prevention (DHP), National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), CDC, in collaboration with health departments in the states, the District of Columbia, and U.S. dependent areas, conducts national surveillance for cases of HIV infection that includes critical data reported across the spectrum of HIV disease stages from HIV diagnosis to death. NHSS data collection activities are currently supported through cooperative agreements with health departments under CDC Notice of Funding Opportunity PS24 – 0047: High-Impact HIV Prevention and Surveillance Programs for Health Departments CDC-RFA-PS-24-0047 and Accelerating the Prevention and Control of HIV, Viral Hepatitis, STDs, and TB in the U.S. Affiliated Pacific Islands CDC-RFA-PS23-2302.

The systematic data collection in NHSS provides the essential data used to calculate population-based HIV incidence estimates, describe the geographic distribution of disease, monitor HIV transmission and drug resistance patterns and genetic diversity of HIV among infected persons, detect and respond to HIV clusters of recent and rapid transmission, and monitor perinatal exposures. NHSS data are also used locally to identify persons with HIV who are not in medical care and linking them to care and needed services. Describing geographic distribution allows CDC to assess social determinants of health in the context of HIV which allows identification health inequities, and guides steps to address and monitor the health equity over time moving forward. NHSS data continue to be collected, maintained, and reported using standard case definitions, report forms and software. The system is periodically updated to keep pace with changes in testing technology and advances in HIV care and treatment, as well as changing prevention program monitoring, evaluation and response needs.

The changes requested in this Revision include program-initiated modifications to currently collected data elements and forms including changes to the Initial, Follow-up, and Annual/Closeout Cluster Report Forms (CRFs). Changes are being made to better address the

current challenges and implementation of cluster response. There is no change to the purpose, use, or methods of data collection, as outlined in the previously submitted Supporting Statement Parts A and B. These modifications of questions will add depth and result in more accurate and complete responses. Revisions were made to simplify data collection and entry for health departments, to collect more relevant data that would help health departments track progress in responding to HIV clusters, and to help health departments better communicate their progress and challenges to CDC so that CDC can provide more effective technical assistance and other support for responding to clusters and outbreaks.

Revisions were guided by discussions with health departments. In 2024, CDC hosted three webinars about changes to the forms that were open to all health departments expected to submit CRFs. CDC also sent draft revised CRFs to health departments to solicit written feedback on the changes. CRFs were streamlined by removing data elements felt by health departments to be particularly difficult to populate, or which were no longer needed. Some were replaced with data elements that will capture the information more accurately and in a way that provides health departments more flexibility about which data elements to report, depending on the context of the cluster. Some questions and instructions within the form were modified to improve the quality of data collected, based on experience and data gathered since the last ICR submission.

This Revision also standardizes questions across the three CRFs (initial, follow-up, and annual/closeout) to make it a more consistent experience for health departments to complete the forms. The Revision removes a rigid set of outcome questions related to three specific activities (testing partners of cluster members for HIV, linking cluster members to treatment, and referring partners of cluster members to pre- or post-exposure prophylaxis) that were included in the initial and annual/closeout CRFs and instead substitutes more open-ended outcome questions representing the full range of potential response activities in just the annual/closeout CRFs. This

Revision will allow health departments more flexibility in reporting outcomes for the activities that they felt were most important to implement in the cluster response.

The number of questions answered varies due to skip patterns and optional questions that health departments may elect to answer or skip, and has been reduced in each of the three CRFs, as shown below.

<b>Form</b>		<b>Currently approved</b>	<b>Proposed revision</b>
Initial	Total questions	57	32
	Required questions	21-43	13-25
Follow-up	Total questions	25	20
	Required questions	20	4-17
Annual/Closeout	Total questions	39-42	39
	Required questions	28	21-32

Cluster report forms will be captured via REDCap, a secure web application for building and managing online surveys and databases. REDCap allows for auto-population of several fields and reduces burden on health departments, who previously needed to encrypt and upload Excel files.

There will be no increase or decrease in the number of respondents for the CRFs. The overall number of required questions will be reduced though the overall burden will remain the same, as additional detail will be asked in some of the remaining questions. OMB approval is requested for three years. The total estimated annualized burden is 60,731 hours for NHSS, including the CRFs. There are no costs to the respondents other than time.

#### Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
Health Departments	Adult HIV Case Report (ACRF)	59	789	20/60
Health Departments	Perinatal Exposure and Pediatric HIV Case Report (PCRF)	59	57	35/60

Health Departments	Case Report Evaluations	59	85	20/60
Health Departments	Case Report Updates	59	2519	2/60
Health Departments	Laboratory Updates	59	10,130	0.5/60
Health Departments	Deduplication Activities	59	3,032	10/60
Health Departments	Investigation Reporting and Evaluation	59	929	1/60
Health Departments	Initial Cluster Report Form	59	2.5	1
Health Departments	Follow-Up Cluster Report Form	59	5	0.5
Health Departments	Annual/Closeout Cluster Report Form	59	2.5	1
Health Departments	Annual Reporting Standards Evaluation Report (SER)	59	1	8

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[FR Doc. 2025-10620 Filed: 6/10/2025 8:45 am; Publication Date: 6/11/2025]