Justification for Change
National HIV Surveillance System (NHSS) OMB # 0920-0573

Summary of Changes

We are requesting a change in the information collection request (ICR) for the National HIV Surveillance System (NHSS) OMB #0920-0573 associated with the reinstating of HIV incidence surveillance activities under a new funding announcement PS20-2010 *Integrated HIV Programs for Health Departments* to support ending the HIV epidemic in the United States. The Ending the HIV Epidemic (EHE) initiative is intended to build on the on-going activities funded through *PS18-1802: Integrated HIV Surveillance and Prevention Programs for Health Departments* to strategically advance (i.e., initiate new or expand existing) HIV prevention efforts. Component B of the NOFO funds HIV incidence surveillance activities in selected jurisdictions using a recency assay. The funded jurisdictions include Alabama, District of Columbia, Florida, Michigan, New York City, South Carolina and Texas and Houston. These jurisdictions met PS20 2010 eligibility requirements for HIV Incidence surveillance activities including having >300 new HIV diagnoses annually, having produced reliable incidence estimates from the currently used CD4-based statistical models, and demonstrated previous success in implementing recency assay-based HIV incidence surveillance. It is anticipated that incidence surveillance reporting for both Houston and the rest of the state of Texas will be done through the state health department, therefore burden calculations for this ICR include 7 jurisdictions: Alabama, District of Columbia, Florida, Michigan, New York City, South Carolina and Texas (including Houston).

Since 2018, HIV Incidence surveillance activities were scaled back, and CDC began using a CD4-based statistical model for incidence estimation to allow for incidence estimation nationwide. Consequently, the estimated burden for incidence surveillance was removed from this ICR in 2019. In 2021, eight previously funded programs will begin conducting HIV incidence surveillance activities again, estimating HIV incidence using a recent infection testing algorithm (RITA) based on test results, testing history, and clinical information that have continued to be reported as part of routine surveillance and collection of previously approved variables for specimen tracking and estimation. Since the goals of EHE are to reduce new HIV infections, accurate calculation of incidence is critical for measuring the success of prevention efforts. This incidence surveillance activity will help CDC and state health departments address whether potential increases in HIV diagnoses represent new infections or diagnoses of longstanding chronic infections finally being identified, as well as enable comparison of the currently used statistical methods using the CD4-based model and identification of best practices for incidence estimation.

Most variables necessary for incidence calculations, including diagnosis information, HIV test-related laboratory data, testing history, and antiretroviral use information are currently being collected as part of routine HIV surveillance and reported to CDC in the NHSS reporting system. Additional variables used to track recency results for RITA (also referred to as serologic testing algorithm for recent HIV seroconversion (STARHS)-related variables) needed to estimate incidence will be collected again and reported to CDC. See table 1 for variables for which collection will be resuming. Note variables in Table 1 are currently included in the electronic database only and do not appear on the Adult Case Report Form (ACRF). Table 1 only includes variables specific to recency tests for STARHS and does not include other variables that are not specific to RITA or STARHS that would be entered routinely as part of any laboratory report document (See Attachment 3(c) Data Elements for the National HIV Surveillance System for other routinely reported laboratory variables).

Table 1. Variables specific to the Serologic Testing Algorithm for Recent HIV Seroconversion (STARHS) previously approved that will be used for Incidence Surveillance

Variable name	Description	Valid Values
lab_test_cd	The data system defined codes to identify lab tests.	Specific values related to STARHS assay will be collected again (notably, EC-025 [STARHS Avidity]): EC-023 (STARHS [BED]) EC-024 (STARHS [Vironostika]) EC-025 (STARHS [Avidity]) EC-026 (STARHS [Other]) EC-027 (STARHS [Unknown])
result	The result value, including the optical density for STARHS. For results related to a STARHS assay, the best available STARHS result from the result variable is used to create the calculated variable, starhs_result, for analysis.	For STARHS assay, a value of up to 10 alphanumeric characters
result_interpretation	An interpretation of the lab result. For values related to a STARHS assay, the best available STARHS result interpretation from the result_interpretation variable.is used to create the calculated variable, starhs_interpretation, for analysis.	Specific values related to STARHS assay will be collected again: 01 (Long Term) 02 (Recent) 91 (Quantity not sufficient) 92 (Specimen never received) 93 (Broken in transit) 94 (Other, indeterminate) 95 (Not sufficient antibodies) 99 (Undefined result)
sample_dt	The date the specimen was collected. For specimen collection dates related to a STARHS assay, the best available specimen collection date from the sample_dt variable is used to create the calculated variable, starhs_sample_dt, for analysis.	YYYYMMDD
starhs_sample_id	If this is a confirmatory test aliquoted for STARHS, STARHS specimen ID.	A string of characters and numbers up to 15 characters
sreason	Reason specimen not sent for recency testing (e.g., STARHS).	1 (Quantity not sufficient) 2 (Specimen never received at public lab) 3 (Specimen broke in transit) 4 (Other) 5 (Not sufficient antibodies)

Changes in Estimates of Annualized Burden Hours

We are requesting an additional 1,331 burden hours to resume incidence activities in EHE jurisdictions. We estimate an overall increase in total estimated annualized burden hours for this ICR from 58,131 hours to 59,462 resulting from the resumption of incidence surveillance activities in 7 reporting health departments. This 2.2% increase accounts for burden associated with sorting and tracking of specimens, additional data entry and processing of electronic results back into the HIV reporting system, and additional burden to follow-up to complete missing testing and treatment information if not reported completely through routine surveillance activities. We have reduced the time for response for HIV incidence activities from previous ICRs (from 10 minutes to 5 minutes) to account for improvements in electronic reporting and data collection for some of these variables that is already accounted for in the burden estimate for routine case reporting (e.g., under ACRF, laboratory updates and case report updates).

Exhibit 12.A Estimate of Annualized Burden Hours.

Form Name	No. of Respondents	No. of Responses per Respondent	Total No. of Annual Responses	Avg. Burden per Response (in hours)	Total Annual Burden (in hours)
Adult HIV Case Report(att 3a,3c,4a)	59	854	50,386	20/60	16,795
Pediatric HIV Case Report (att 3b,3c,4b)	59	3	177	20/60	59
Case Report Evaluations (att 3a,3b,3c)	59	86	5,074	20/60	1,691
Case Report Updates (att 3a,3b,3c,4a,4b)	59	2353	138,827	2/60	4,628
Laboratory Updates (att 3a,3b,3c,4a,4b)	59	9410	555,190	0.5/60	4,627
Deduplication Activities (att 4c)	59	2741	161,719	10/60	26,953
Investigation Reporting and Evaluation (att 3c,4d,4e)	59	901	53,159	1/60	886
Initial Cluster Report Form (att 3f,4f)	59	2.5	148	1	148
Cluster Follow-	59	5	295	30/60	148

up Form (att 3g,4f)					
Cluster Close-out Form (att 3h, 4e)	59	2.5	148	1	148
Perinatal HIV Exposure Reporting (PHER) (att 3c,3d,4b)	16	197	3,152	30/60	1,576
HIV Incidence Surveillance (HIS) (att. 3a, 3c, 4a)	7	2,282	15,974	5/60	1,331
Annual Reporting: Standards Evaluation Report (SER) (att 3e)	59	1	59	8	472
Total Burden					59,462

Note: The estimates of total annualized burden hours are based on the estimated total number of case reports (i.e., Total No. Annual Responses) expected to be completed by state and local health departments each year (see narrative for description)