case, cluster, and outbreak prevention and control strategies. CRF data elements and the CRF were designed for administration via telephone interviews with individuals ill with cryptosporidiosis, or their designated proxy.

CDC requests OMB approval for an estimated 125 annual burden hours. Providing information is voluntary, and there are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Individuals ill with cryptosporidiosis, or their designated proxy.	CryptoNet Case Report Form	500	1	15/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2025–00162 Filed 1–7–25; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–25–1357; Docket No. CDC–2024–0104]

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 continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project 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). This study will identify facilitators and barriers with implementation of HIV point-of-care (POC) nucleic acid tests (NATs) in clinical settings, estimate the sensitivity and specificity of the HIV POC NAT, and assess the impact of the test in decreased time to receipt of HIV prevention and care.

DATES: CDC must receive written comments on or before March 10, 2025.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2024–0104 by either of the following methods:

- *Federal eRulemaking Portal: 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 H21–8, Atlanta, Georgia 30329.

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

Please note: Submit all comments through the Federal eRulemaking portal (*www.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 H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *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;
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; and
5. Assess information collection costs.

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, Exp. 12/31/2024)—Reinstatement—National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC)

Background and Brief Description

HIV prevention and care services can be improved by the availability of Point-of-care (POC) HIV viral RNA testing in clinical settings. Viral RNA tests are the most sensitive HIV tests for the detection of early infection. The purpose of this data collection is to develop feasible and effective models to integrate HIV POC nucleic acid tests (NATs) in HIV prevention and treatment services. The HIV POC NAT can be used to test persons at high-risk of acquiring HIV infection to reduce the time

between testing in community-based and clinical-based settings and linkage to HIV care, ART initiation, and viral suppression.

Data will be used to compare an HIV RNA POC NAT to standard lab-based HIV testing. The data will be analyzed and disseminated to describe the real-world performance and clinical usefulness of HIV RNA POC NAT technology. Data will be gathered through: clinical site extraction of electronic medical records for use as a retrospective baseline comparator after study implementation; a longitudinal, prospective study of persons without HIV seeking HIV testing or PrEP services; a longitudinal, prospective study of persons with HIV seeking STI testing; a randomized clinical trial of HIV POC NAT or standard of care for persons with HIV; a survey, interviews, and focus groups to understand HIV POC NAT acceptability among persons without HIV and persons with HIV; an assessment of the performance of an HIV POC NAT among persons with HIV; and an acceptability/feasibility assessment among clinical and community providers and costing analyses.

CDC is requesting OMB approval for estimated 880 annual burden hours. There are no costs to respondents 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 hours)	Total burden (in hours)
Participating Clinic	Baseline data collection variables list.	2	1	2	4
	Monthly study report form	2	12	15/60	6
Participants in prospective study of persons without HIV seeking HIV testing and/or PrEP services.	Release of information form	850	1	10/60	142
	Study visit survey	850	1	15/60	213
Participants in prospective study of persons with HIV seeking STI testing.	Release of information form	50	1	10/60	8
	Study visit survey	50	1	15/60	13
Participants in RCT of POC NAT or Standard of Care for persons with HIV.	Release of information form	212	1	10/60	35
	Study visit survey	212	1	15/60	53
Participants in survey group examining POC NAT acceptability.	POC NAT acceptability survey	500	1	20/60	167
Participants in cross-sectional comparison of several point-of-care NATs.	Release of information form	333	1	10/60	56
	Study visit survey	333	1	15/60	83
Participants in the acceptability/feasibility assessment.	POC NAT acceptability survey, focus group, or interview.	100	1	1	100
Total					880

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

Food and Drug Administration

[Docket No. FDA–2007–D–0435]

Obesity and Overweight: Developing Drugs and Biological Products for Weight Reduction; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Obesity and Overweight: Developing Drugs and Biological Products for Weight Reduction.'' This draft guidance provides recommendations to industry regarding the development of drugs and biological products regulated within the Center for Drug Evaluation and Research intended for reduction and long-term maintenance of body weight in patients with obesity or overweight. This draft guidance revises and replaces the draft guidance for industry ''Developing Products for Weight Management'' issued in February 2007.

DATES: Submit either electronic or written comments on the draft guidance by April 8, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your