



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-25-1313; Docket No. CDC-2025-0387]

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 Distribution of Traceable Opioid Material® Kits (TOM® Kits) across U.S. and International Laboratories. The purpose of this information collection request (ICR) is for the CDC to assure that the Traceable Opioid Material® Kits (TOM® Kits) are equitably distributed to domestic and international partner laboratories, and to allow CDC to understand the types of laboratories requesting these materials and the analyses that are being conducted.

DATES: CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2025-0387 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; E-mail: 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

Distribution of Traceable Opioid Material® Kits (TOM® Kits) across U.S. and International Laboratories (OMB Control No. 0920-1313, Exp. 3/31/2026) – Extension – National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purpose of this information collection request (ICR) is for the CDC to assure that the Traceable Opioid Material® Kits (TOM® Kits) are equitably distributed to domestic laboratory sectors (public, private, and non-profit) and to international partner laboratories. This collection will enable CDC to gather information on the types of laboratories requesting Traceable Opioid Material® Kits and to determine the types of sample analyses that are being conducted by these laboratories through use of these kits.

CDC requests OMB approval for an estimated 80 annual burden hours. There is no cost 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)	Total Burden (in hours)
US Federal Laboratories	Test Kit Application and Questions for US Laboratories	200	1	6/60	20

	(online)				
State, Local, and Tribal Government Laboratories	Test Kit Application and Questions for US Laboratories (online)	200	1	6/60	20
Private or Not-for-Profit US Institutions	Test Kit Application and Questions for US Laboratories (online)	200	1	6/60	20
International Laboratories	Test Kit Questions for International Laboratories	300	1	5/60	20
Total					80

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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