

Setting

- Any, including single- and multicenter

Design

- RCTs, N≥10 per group
- NRCs, N≥30 per group
- Case-control studies, N≥100 per group
- Single group studies, N≥500
- Studies may be prospective or retrospective
- *Exclude:* case reports and series of individually-reported case reports

Dated: June 26, 2020.

Virginia Mackay-Smith,

Associate Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-20-20EC]

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 Enterprise Laboratory Information Management System (ELIMS) 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 December 23, 2019 to obtain comments from the public and affected agencies. CDC received one comment 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:

- 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;
- 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

Enterprise Laboratory Information Management System (ELIMS) Existing Collection in Use Without an OMB Control Number—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The collection of specimen information designated for testing by the CDC occurs on a regular and recurring basis (multiple times per day) using an electronic PDF file called the *CDC Specimen Submission 50.34 Form* or an electronic XSLX file called the *Global File Accessioning Template*. Hospitals, doctor’s offices, medical clinics, commercial testing labs, universities, state public health laboratories, U.S. federal institutions and foreign institutions use the *CDC Specimen*

Submission Form 50.34 when submitting a single specimen to CDC Infectious Diseases laboratories for testing. The *CDC Specimen Submission 50.34 Form* consists of over 200 data entry fields (of which five are mandatory fields that must be completed by the submitter) that captures information about the specimen being sent to the CDC for testing. The type of data captured on the *50.34 Form* identifies the origin of the specimen (human, animal, food, environmental, medical device or biologic), CDC test order name/code, specimen information, patient information (as applicable), animal information (as applicable) information about the submitting organization requesting the testing, patient history (as applicable), owner information and animal history (as applicable) and epidemiological information. The collection of this type of data is pertinent in ensuring a specimen’s testing results are linked to the correct patient and the final test reports are delivered to the appropriate submitting organization to aid in making proper health-related decisions related to the patient. Furthermore, the data provided on this form may be used by the CDC to identify sources of potential outbreaks and other public-health related events. When the form is filled out, a user in the submitting organization prints a hard copy of it that will be included in the specimen’s shipping package sent to the CDC. The printed form has barcodes on it that allow the CDC testing laboratory to scan its data directly into ELIMS where the specimen’s testing lifecycle is tracked and managed.

Likewise, the *Global File Accessioning Template* records the same data as the *50.34 Form* but provides the capability to submit information for a batch of specimens (typically 50–1,000 specimens per batch) to a specific CDC laboratory for testing. The CDC testing laboratory electronically uploads the *Global File Accessioning Template* into ELIMS where the batch of specimens are then logged and are ready to be tracked through their respective testing and reporting workflow. There is no cost to respondents other than their time. The total burden hours are 2,131 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Medical Assistant, Doctor's Office/Hospital	CDC Specimen Submission 50.34 Form	2,000	3	5/60
19-1042 Medical Scientists, Except Epidemiologists, State Public Health Lab.	CDC Specimen Submission 50.34 Form	98	193	5/60
Medical Assistant, Doctor's Office/Hospital	Global File Accessioning Template	15	11	20/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, 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

[60Day-20-20PJ; Docket No. CDC-2020-0073]

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 proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled "Formative Research on Community-Level Factors that Promote the Primary Prevention of Adverse Childhood Experiences (ACEs) and Opioid Misuse Among Children, Youth, and Families in Tribal American Indian and Alaska Native (AI/AN) Communities." The proposed collection is designed to conduct formative qualitative studies to identify community-level protective factors and primary prevention strategies across a range of Tribal communities to prevent adverse childhood experiences (ACEs) and opioid misuse.

DATES: CDC must receive written comments on or before August 31, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2020-0073 by any of the following methods:

- *Federal eRulemaking Portal:* <http://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-D74, Atlanta, Georgia 30329.

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

Please note: Submit all comments through the Federal eRulemaking portal (<http://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-D74, Atlanta, Georgia 30329; phone: 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; and

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.

5. Assess information collection costs.

Proposed Project

Formative Research on Community-Level Factors That Promote the Primary Prevention of Adverse Childhood Experiences (ACEs) and Opioid Misuse Among Children, Youth, and Families in Tribal American Indian and Alaska Native (AI/AN) Communities—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC)

Background and Brief Description

Adverse childhood experiences (ACEs) are preventable, potentially traumatic events that occur in childhood (0-17 years) such as experiencing violence, abuse, or neglect; witnessing violence in the home; and having a family member attempt or die by suicide. There is a robust evidence base linking ACEs to a variety of poor health outcomes across the life span, including depression, alcohol and substance use disorder, and violence perpetration and victimization. The ongoing opioid epidemic is a complex and significant public health crisis that exposes children to opioid misuse, violence, and other ACEs, and challenges the ability of Health and Human Service (HHS) systems to mitigate the effects of opioid misuse and ACEs on children and families across the U.S. American Indian/Alaska Native (AI/AN) populations experience a disproportionate burden of opioid misuse and ACEs, and ACE-related