Proposed Project

Institutional Review Board Authorization Agreement for Human Research—New—Office of Science (OS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC Human Research Protection Office (HRPO) often receives requests from outside institutions seeking to rely on the CDC Institutional Review Board (IRB) for review of a research study. This arrangement also allows multiple institutions to use, or rely on, the CDC IRB for centralized review and approval of research studies instead of review by the site-specific IRBs, which helps reduce duplication of effort, delays, and expenses. To meet regulatory requirements, institutions that elect to rely on the CDC IRB are required to complete a CDC IRB Authorization Agreement for Human Research and a Local Context Survey. The goal is to use the agreement and survey to provide regulatory oversight for human subjects research, to maintain records, and to track those institutions that have elected to rely on the CDC IRB for review.

CDC requests OMB approval for an estimated 450 annual burden hours. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number responses per respondent	Avg. burden per response (in hrs.)
Hospital/Academic Institutions/IRB Administrators.	CDC IRB Authorization Agreement for Human Research (for review, completion, and submission to CDC).	150	1	1
Hospital/Academic Institutions/IRB Administrators.	Local context survey (for completion and submission to CDC).	150	1	2

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. 2024–21571 Filed 9–19–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–24–1365; Docket No. CDC–2024–0069]

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 Program Evaluation of CDC's Core State Injury Prevention Program. This project allows CDC to collect information from awardees funded under the Core State Injury Prevention Program.

DATES: CDC must receive written comments on or before November 19, 2024.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2024–0069 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

Program Evaluation of CDC's Core State Injury Prevention Program (OMB Control No. 0920–1365, Exp. 7/31/2025)—Revision—National Center for Injury Prevention and Control (NCIPC),

Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is submitting a Revision request for the currently approved Program Evaluation of CDC's Core State Injury Prevention Program (OMB Control No. 0920–1365, Expiration Date 7/31/2025). Approval is requested for an additional three years to continue collecting information from awardees funded under the Core State Injury Prevention Program cooperative agreement (CE21–2101), hereafter known as Core SIPP.

CDC requests to continue collecting several types of information from recipients over the course of the funding cycle. The Core SIPP Program added three new recipients to the program and is requesting a revision to allow for data collection of these three new recipients. This Revision is requested to incorporate data collection and analysis of three new funded recipients who were added. Data collected up until this point has been used to inform technical assistance (TA) to recipients and programmatic decision-making. CDC has used this data to develop reports to show program impact on recipient capacity, public health actions, and continuous quality improvement. This information will continue to be used to:

(1) Evaluate and track outcomes at the recipient- and program-levels as they relate to injury prevention-focused infrastructure development, surveillance system development and use, and partnerships to prevent Adverse Childhood Experiences (ACEs), Traumatic Brain Injury (TBI), and transportation-related injuries. Recipient-and program-level identification of disproportionately affected populations and subsequent public health actions taken to address injury-related health disparities will also be assessed.

(2) Identify TA needs of individual recipients and the recipient cohort, so that the CDC team can appropriately deploy resources to support recipients.

(3) Identify practice-based evidence for injury prevention public health actions to advance the field through future partnerships, program design, and publications.

(4) Inform continuous quality improvement activities over the course of the funding period, to include quarterly and annual strategic planning for current and later iterations of this program under future funding.

Information is collected by CDC through the following modes to address the purposes identified above:

(1) The Core SIPP Implementation Capacity Development Rubric was implemented once at the start of program funding (baseline collection), and subsequently during the middle of each reporting year. Recipients self-administer the rubric via CDC's Partner Portal, where they self-score their state injury prevention programs according to their current level of capacity for components of interest. These scores are used to identify recipient strengths, areas for improvement, and additional needs for CDC TA support. Measuring recipient improvements in implementing public health actions in this standard way greatly increases the ability for CDC to measure the impact of the program investment. CDC aggregates these scores across recipients to identify larger program needs and to inform internal Continuous Quality Improvement (CQI) activities. This information is shared back with recipients individually during annual technical review calls, as well as in aggregate at annual partnership meetings. Additionally, increased capacity will increase the likelihood of sustainability beyond the funding cycle.

(2) Recipient-level Group Interviews will take place at the end of Program Years 3, 4, and 5. The purpose of these interviews is to evaluate progress and challenges in implementing the Core SIPP program within the individual recipient-level context to inform tailored supports from CDC and partners. The tailored support is an effort to facilitate solutions to programmatic barriers, adjust recipient strategies as needed, and ensure the quality of data reported annually to CDC.

(3) Economic Indicators are collected to better understand the cost of IVP implementation by strategy as well as how recipients have leveraged funds and resources to increased sustainability for injury and violence prevention work.

(4) Injury Indicator Spreadsheets and Special Emphasis Reports are collected annually to track state level injury and violence morbidity and mortality data. This allows CDC to measure trends over time within a state, across states, and against the national average to identify changes during the Core SIPP funding period. Completion of the spreadsheets and reports ensures recipient surveillance capacity and reporting is in alignment with best practices.

CDC requests OMB approval for an estimated 764 annual burden hours. There is no cost to respondents other than their time to participate.

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)
Core SIPP Program Awardees	Implementation Capacity Rubric	26	1	2	52
	Economic Indicators	23	1	1	23
	Recipient-level Group Interviews	26	1	1.5	39
	Injury Indicators Spreadsheet	26	1	5	130
	Emergency Department Injury Indicators Spreadsheet.	26	1	5	130
	Hospital Discharge Injury Indicators Spreadsheet.	26	1	5	130
	Special Emphasis Reports	26	1	10	260
Total					764

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. 2024–21570 Filed 9–19–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Announcing the Intent To Award a Sole Source Supplement to the National Association of Councils on Developmental Disabilities (NACDD)

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing the award of a sole-source supplement for the Bridging Aging and Disability Networks cooperative agreement. ACL's Office of Supportive and Caregiver Services (OSCS), Administration on Aging (AoA) is collaborating with the Projects of National Significance, the Administration on Disabilities (AoD) to provide a $180,478 supplement to the Bridging Aging and Disability grant. This grant is awarded to the NACDD, who is partnering with the Institute on Disability and Human Development at the University of Illinois-Chicago, the Lurie Institute for Disability Policy at Brandeis University, The Arc, and US Aging—the national association representing and supporting the network of Area Agencies on Aging (AAAs) and Title VI Native American Aging Programs. The goal of the grant is to strengthen the collaboration between aging and disability networks to better support individuals with intellectual and developmental disabilities (I/DD) and their family caregivers in future planning as they age. The supplemental funding will be used to additionally support aging caregivers of adults with I/DD and will enhance the work of the 17 State Consortia teams to more directly build capacity of AAAs to serve adults with I/DD as they age and their aging caregivers. The administrative supplement for FY 2024 will be in the amount of $180,478, bringing the total award for FY 2024 to $600,000.00.

FOR FURTHER INFORMATION CONTACT: For further information or comments regarding this program supplement, contact Larissa Crossen, U.S. Department of Health and Human Services, Administration for Community Living, telephone (202) 795–7333; email *Larissa.crossen@acl.hhs.gov*

SUPPLEMENTARY INFORMATION: The purpose of the supplemental funding is to additionally support aging caregivers of adults with I/DD and will enhance the work of the 17 State Consortia teams. A portion of the funding (estimated 50%) will be used to pay for existing workplan activities of the grantee, particularly where there is overlap in the existing work to bridge the aging and disability networks to support aging caregivers of adults with I/DD. The remainder of the funding (estimated to be 50%) will be used to enhance the work of the 17 State Consortia teams to more directly build capacity of AAAs to serve adults with I/DD as they age and their aging caregivers.

Program Name: Bridging Aging and Disabilities Networks.

Recipient: NACDD.

Period of Performance: The supplement award will be issued for the fourth year of a five-year project period, September 30, 2024, through September 29, 2025.

Award Amount: $180,478.

Award Type: Cooperative Agreement.

Statutory Authority: This program is authorized under the Developmental Disabilities Assistance and Bill of Rights Act of 2000, Title I, Subtitle E.

CFDA Number: 93.631 Discretionary Projects.

Basis for Award: NACDD is currently funded to carry out the objectives of this project, Bridging Aging and Disability Networks, and has completed three years of work. ACL believes it is in the best interest of the Federal Government to supplement the current grantee's existing project. Establishing a new grant project at this time would be potentially disruptive to the current work already well under way. Further, it could create unintended duplication of effort and missed opportunities for greater coordination between the aging and disability networks.

Dated: September 16, 2024.

Alison Barkoff,

Principal Deputy Administrator for the Administration for Community Living, performing the delegable duties of the Administrator and the Assistant Secretary for Aging.

[FR Doc. 2024–21498 Filed 9–19–24; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–4165]

Chemical Analysis for Biocompatibility Assessment of Medical Devices; Draft Guidance for Industry and Food and Drug Administration Staff; 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 the draft guidance entitled ''Chemical Analysis for Biocompatibility Assessment of Medical Devices.'' FDA is issuing this draft guidance to describe recommended methodological approaches for chemical analysis for biocompatibility assessment of medical devices. The biocompatibility of medical devices is evaluated based on the duration of exposure and nature of contact with the body. Chemical characterization is one approach that manufacturers can consider when developing a strategy for the overall biocompatibility assessment of a device. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by November 19, 2024 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 comments, that information will be posted on *https://www.regulations.gov.*