e: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-24-24AH; Docket No. CDC-2023-0087]

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 to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled IRB Authorization Agreement for Human Research. The purpose of the data collection is to keep track of, and provide regulatory oversight for, those institutions that have elected to rely on the CDC IRB's review of research studies.

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

ADDRESSES: You may submit comments, identified by Docket No. CDC-2023-0087 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

IRB 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's review of research studies are required to complete a CDC IRB Authorization Agreement for Human Research and a Local Context Survey. The agreement and the survey will be used to provide regulatory oversight for human subjects research, maintain records and 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	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Hospital/Academic Institutions/IRB Administrators	CDC IRB Authorization Agreement for Human Research (for review, completion and submission to CDC)	150	1	1	150

Hospital/Academic Institutions/IRB Administrators	Local context survey (for completion and submission to CDC	150	1	2	300
Total					450

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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