



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request

NIH Electronic Application System for NIH Certificates of Confidentiality (CoC)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the Office of Extramural Research (OER), in the Office of the Director (OD), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written 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.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Pamela Reed Kearney, Director, Division of Human Subjects Research, OER, NIH, 6705 Rockledge Dr., Building Rockledge 1, Room 812-C, Bethesda, MD 20817, or call non-toll-free number (301) 402-2512 or E-mail your request, including your address to: NIH-CoC-Coordinator@mail.nih.gov.

SUPPLEMENTARY INFORMATION: This proposed information collection was

previously published in the *Federal Register* on April 16, 2025, page 15989 (90 FR 15988) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The Office of Extramural Research (OER), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: Electronic Application for NIH Certificates of Confidentiality (CoC E-application System), 0925–0689, REINSTATEMENT WITHOUT CHANGE, exp., date 04/30/2025. Office of Extramural Research (OER), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of this electronic system is to submit and process of requests for NIH to issue a discretionary Certificates of Confidentiality (CoC) to all research organizations that request a CoC from NIH. As described in the authorizing legislation (Section 301(d) of the Public Health Service Act, 42 U.S.C. 241(d)), CoCs are issued by the agencies of Department of Health and Human Services (DHHS), including NIH, to authorize researchers to protect the privacy of human research subjects by prohibiting them from releasing names and identifying characteristics of research participants to anyone not connected with the research, except in limited circumstances specified in the statute. At NIH, the issuance of CoCs has been delegated to the NIH Office of Extramural Research (OER) in the NIH Office of the Director. The NIH has been using an online CoC system to review requests and issue

CoCs since 2015. The current CoC request form includes 27 questions to collect information from research organizations and six Institutional Assurance statements to be affirmed by the Institutional Official. The information provided is used to determine eligibility for a CoC and to issue the CoC to the requesting organization. Eligible requesting organizations that provide legally binding affirmations that they will abide by the terms of the CoC are issued a Certificate of Confidentiality. This system has increased efficiency and reduced burden for both requesters and NIH staff who currently process these requests. NIH received 865 requests for CoCs from January 2024 through December 2024 and expects to receive approximately the same number of requests in subsequent years.

OMB approval is requested for three years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,298.

Estimated Annualized Burden Hours

Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Time Per Response (in hours)	Total Annual Burden Hour
Individuals	865	1	90/60	1,298
TOTAL		865	--	1,298

Dated: July 3, 2025.

Matthew Memoli,

Principal Deputy Director,

National Institutes of Health.