



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Proposed Collection; 60-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 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 60 days of the date of this publication.

**FOR FURTHER INFORMATION CONTACT:** To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, E-mail your comment or request, including your address to: [NIH-CoC-Coordinator@mail.nih.gov](mailto:NIH-CoC-Coordinator@mail.nih.gov) or contact: Dr. Pamela Reed Kearney, 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. Formal requests for additional plans and instruments must be requested in writing.

**SUPPLEMENTARY INFORMATION:** Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance

of the function of the agency, including whether the information will have practical utility; (2) 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) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*Proposed Collection Title:* Electronic Application for NIH Certificates of Confidentiality (CoC E-application System), 0925-0689, REVISION, 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 requests for NIH to issue discretionary Certificates of Confidentiality (CoC) to research organizations requesting CoCs from NIH that align with the NIH research mission. 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 the 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 discretionary CoCs since 2015. The current CoC online 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 discretionary CoC and to determine eligibility for issuance of 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 915 requests for CoCs from January 2023 through December 2023 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 1,373.

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	915	1	90/60	1,373
TOTAL		915	--	1,373

**Dated:** April 10, 2025.

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