



**[BILLING CODE 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Proposed collection; 60-day comment request**

**Requests for NIH Certificates of Confidentiality**

**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, the National Institutes of Health (NIH) is streamlining the electronic system for the submission and processing of requests for NIH to issue Certificates of Confidentiality (CoCs).

**DATE:** 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, 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, or e-mail your request, including your address to: NIH-CoC-Coordinator@mail.nih.gov. 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, exp., date 12/31/2019 REVISION. Office of Extramural Research (OER), National Institutes of Health (NIH).

Need and Use of Information Collection: This request system provides one electronic form to be used by all research organizations that request a Certificate of Confidentiality (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 OER in the NIH Office of the Director. NIH received 529 requests for CoCs from April 2017 through March 2018 and expects to receive approximately the same number of requests in subsequent years. The NIH has been using an online CoC system to review requests and issue CoCs since 2015. The current CoC request form includes 15 sections of information collected from research organizations. The streamlined NIH CoC electronic system will have seven sections of structured or short text fields. The information provided will be 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 would be issued a Certificate of Confidentiality. This system is expected to increase efficiency and reduce burden for both requestors and NIH staff who currently process these requests.

OMB approval is requested for three years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 177.

Estimated Annualized Burden Hours

Type of Respondents	Number of Respondents	Number of Responses Per Respondent	Average Time per Response (in hours)	Total Annual Burden Hours
CoC Applicants- Private	372	1	20/60	124
CoC Applicants- State/local	26	1	20/60	9
CoC Applicants- Small business	53	1	20/60	18
CoC Applicants- Federal	78	1	20/60	26
<b>TOTAL:</b>	<b>529</b>			<b>177</b>

Dated: August 7, 2019.

---

Lawrence Tabak,

Principal Deputy Director,

National Institutes of Health.

[FR Doc. 2019-17358 Filed: 8/13/2019 8:45 am; Publication Date: 8/14/2019]