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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-Day Comment Request; NIH Electronic Application System for Certificates of Confidentiality

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with 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.

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/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH.

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, Division of Human Subjects Research, OER, NIH, 6705 Rockledge Dr., Building Rockledge 1, Room 812-C, Bethesda, MD 20817, or email your request, including your address, to: NIH-CoC-Coordinator@mail.nih.gov; telephone number: 301-402-2512.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the Federal Register on August 14, 2019, page 40426-40427 (84 FR 40426) 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 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 December 31, 2019, 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, REVISION, exp., date 12/31/2019, 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 information provided will be used to determine eligibility for a CoC and to issue the CoC to the requesting organization.

OMB approval is requested for three years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 794.

Estimated Annualized Burden Hours

Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Annual Burden Hours
CoC Applicants- Private	372	1	90/60	558
CoC Applicants- State/local	26	1	90/60	39
CoC Applicants- Small business	53	1	90/60	80
CoC Applicants- Federal	78	1	90/60	117
Total		529		794

Dated: December 15, 2019.

Lawrence Tabak,

Principal Deputy Director,

National Institutes of Health.

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