Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911 or Ei Thu Lwin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–0728.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products.'' This guidance complements and expands on the 1998 guidance. The 1998 guidance was issued in response to the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115), which stated that the substantial evidence requirement for effectiveness, which had generally been interpreted as calling for two adequate and well-controlled trials, could also be met by a single trial plus confirmatory evidence. The 1998 guidance, therefore, provided many examples of the types of evidence that could be considered confirmatory evidence, with a specific focus on adequate and well-controlled trials of the test agent in related populations or indications, as well as a number of illustrations of a single adequate and well-controlled trial supported by convincing evidence of the drug's mechanism of action in treating a disease or condition.

FDAMA, thus, introduced a specific new area of flexibility in the evidence needed to support effectiveness, but there are many other characteristics of the evidence supporting effectiveness that can vary (notably, trial designs, trial endpoints, statistical methodology), and evidence that varies in such ways potentially can provide substantial evidence of effectiveness but because of these characteristics may provide greater or lesser certainty. These characteristics also deserve consideration and were not discussed in the 1998 guidance. FDA's use of these various designs, endpoints, and analyses which can differ in the strength of evidence they provide, reflects the Agency's longstanding flexibility when considering the types of data and evidence that can meet the substantial evidence requirement.

Although FDA's evidentiary standard for effectiveness has not changed since 1998, the evolution of drug development and science has led to changes in the types of drug development programs submitted to the Agency. Specifically, there are more programs studying serious diseases lacking effective treatment, more programs in rare diseases, and more programs for therapies targeted at disease subsets. There is a need for more Agency guidance on the flexibility in the amount and type of evidence needed to meet the substantial evidence standard in these circumstances. The approaches discussed in this guidance can yield evidence that meets the statutory standard for substantial evidence and reflect the evolving landscape of drug development.

This guidance discusses the quality of evidence to establish effectiveness, including trial designs and trial endpoints. It also discusses the quantity of evidence needed in a given development program, *i.e.,* two adequate and well-controlled trials, one adequate and well-controlled trial plus confirmatory evidence, or reliance on a previous finding of effectiveness of an approved drug when scientifically justified and legally permissible (*i.e.,* no new effectiveness or pharmacodynamic data would be needed). The guidance also expands upon the discussions included in the 1998 guidance on the types of mechanistic and pharmacologic evidence and non-clinical evidence that can constitute confirmatory evidence.

Although randomized superiority trials with a placebo- or active-control design generally provide the strongest evidence of effectiveness, this guidance discusses the circumstances under which trials not using a placebo control, superiority design, or randomization may be acceptable. In addition, this guidance also discusses situations in which human efficacy trials are not ethical or feasible, and the animal rule may be applied. In all cases, FDA must reach the conclusion that there is substantial evidence of effectiveness to approve a drug; however, the degree of certainty supporting such a conclusion may differ, depending on clinical circumstances (*e.g.,* severity and rarity of the disease and unmet medical need).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 for submission of an investigational new drug application have been approved under OMB control number 0910–0014. The collections of information in 21 CFR 314.50 for submission of an NDA have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 for submission of a BLA have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics,* or *https://www.regulations.gov.*

Dated: December 16, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–27524 Filed 12–19–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 60 Day Information Collection: Indian Health Service Medical Staff Credentials

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments. Request for revision to a collection.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) invites the general public to comment on the information collection titled, ''Indian

Health Service Medical Staff Credentials,'' OMB Control Number 0917–0009, which expires February 29, 2020.

DATES: *Comment Due Date:* February 18, 2020. Your comments regarding this information collection are best assured of having full effect if received within 60 days of the date of this publication.

ADDRESSES: Send your written comments, requests for more information on the collection, or requests to obtain a copy of the data collection instrument and instructions to Juliana Sadovich *by* one of the following methods:

- *Mail:* Juliana Sadovich, Ph.D., RN, CPHQ, Director, Office of Quality, Indian Health Service, 5600 Fishers Lane, Mail Stop: 08N78, Rockville, MD 20857.
- *Phone:* 301–443–4330.
- *Email: Juliana.Sadovich@ihs.gov.*

SUPPLEMENTARY INFORMATION: This notice announces our intent to revise the collection already approved by OMB, and to solicit comments on specific aspects of the information collection. The purpose of this notice is to allow 60 days for public comment to be submitted to IHS. A copy of the supporting statement is available at *www.regulations.gov* (see Docket ID IHS–2019–01).

Information Collection Title: ''Indian Health Service Medical Staff Credentials and Privileges Files, 0917–0009.'' *Type of Information Collection Request:* Extension of an approved information collection, and revised to, ''Indian Health Service Medical Staff Credentials, 0917–0009.'' *Form Numbers:* 0917–0009. *Need and Use of Information Collection:* This collection of information is used to evaluate individual health care providers applying for medical staff privileges at IHS health care facilities. The IHS operates health care facilities that provide health care services to American Indians and Alaska Natives. To provide these services, the IHS employs (directly and under contract) several categories of health care providers including: Physicians (M.D. and D.O.), dentists, psychologists, optometrists, podiatrists, audiologists, physician assistants, certified registered nurse anesthetists, nurse practitioners, and certified nurse midwives. IHS policy specifically requires physicians and dentists to be members of the health care facility medical staff where they practice. Health care providers become medical staff members, depending on the local health care facility's capabilities and medical staff bylaws. There are three types of IHS medical staff applicants: (1) Health care providers applying for direct employment with IHS; (2) contractors who will not seek to become IHS employees; and (3) employed IHS health care providers who seek to transfer between IHS health care facilities.

National health care standards developed by the Centers for Medicare and Medicaid Services, the Joint Commission, and other accrediting organizations require health care facilities to review, evaluate and verify the credentials, training and experience of medical staff applicants prior to granting medical staff privileges. In order to meet these standards, IHS health care facilities require all medical staff applicants to provide information concerning their education, training, licensure, and work experience and any adverse disciplinary actions taken against them. This information is then verified with references supplied by the applicant and may include: Former employers, educational institutions, licensure and certification boards, the American Medical Association, the Federation of State Medical Boards, the National Practitioner Data Bank, and the applicants themselves.

In addition to the initial granting of medical staff membership and clinical privileges, Joint Commission standards require that a review of the medical staff be conducted not less than every two years. This review evaluates the current competence of the medical staff and verifies whether they are maintaining the licensure or certification requirements of their specialty.

The medical staff credentials and privileges records are maintained at the health care facility where the health care provider is a medical staff member. The establishment of these records at IHS health care facilities is a Joint Commission requirement. Prior to the establishment of this Joint Commission requirement, the degree to which medical staff applications were maintained at all health care facilities in the United States that are verified for completeness and accuracy varied greatly across the Nation.

The application process has been streamlined and is using information technology to make the application electronically available via the internet. The IHS is transforming credentialing, which include granting privileges, into a centrally installed, automated, standardized, electronic/digital, measurable, portable, accessible, and efficient business process to improve the effectiveness of application and re-application to Medical Staffs, movement of practitioners within the IHS system, and recruitment/retention of high-quality practitioners. The credentialing process no longer requires paper/pdf forms for granting privileges. The electronic credentialing system incorporates privileges as part of the overall process for credentialing, eliminating the need for paper, and allows tailoring the needs to site specifications. Privileges will differ across IHS Areas and clinics, in compliance with accreditation standards.

The adoption of a central source IT system for medical practitioner staff credentialing/privileging data will enhance the quality, accuracy, and efficiency of the IHS credentialing/privileging process, which is expected to improve the recruitment and retention rates of medical practitioner staff at IHS. Cost savings will be obtained through the termination of disparate business processes; reduction of paperwork duplication; and eliminating systems that do not provide IHS enterprise access to credentialing/privileging information. Additionally, communicating information electronically can reduce costs and errors, promote collaboration, ensure accreditation/privileging requirements are met, and help bring practitioners on board more quickly, which will improve recruitment and retention.

Affected Public: Individuals and households. *Type of Respondents:* Individuals.

The table below provides: Types of data collection instruments, Estimated number of respondents, Number of annual number of responses, Average burden per response, and Total annual burden hours.

Data collection instrument(s)	Estimated number of respondents	Responses per respondent	Average burden hour per response *	Total annual burden (current)
Initial Application to Medical Staff	600	1	0.583 (35 min)	350
Application Packet/Signature Documents	1,300	1	0.167 (10 min)	217
Reappointment Application to Medical Staff	700	1	0.333 (20 min)	233

Data collection instrument(s)	Estimated number of respondents	Responses per respondent	Average burden hour per response *	Total annual burden (current)
Total	2,600			800

* For ease of understanding, burden hours are provided in actual minutes.

Annual number of respondents were factored based on total IHS providers credentialed and privileged on the indicated cycles in the paragraphs above. There are no capital costs, operating costs and/or maintenance costs to respondents.

Requests for Comments: Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry out an agency function; (b) whether the agency processes the information collected in a useful and timely fashion; (c) the accuracy of public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information); (d) whether the methodology and assumptions used to determine the estimate is logical; (e) ways to enhance the quality, utility, and clarity of the information being collected; and (f) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Chris Buchanan,

Deputy Director, RADM, Assistant Surgeon General, USPHS, Indian Health Service.

[FR Doc. 2019–27442 Filed 12–19–19; 8:45 am]

BILLING CODE 4165–16–P

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