FDA website listed in the previous sentence to find the most current version of the guidance.

III. Paperwork Reduction Act

This draft guidance refers to previously approved collections of information found in FDA regulations.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 101.36 have been approved under OMB control number 0910–0381.

Dated: August 31, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19367 Filed 9–6–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Charter Renewal for the Advisory Committee on Organ Transplantation

AGENCY: Health Resources and Services Administration (HRSA), The Department of Health and Human Services (HHS).

ACTION: Notice of charter renewal.

SUMMARY: HHS is hereby giving notice that the Advisory Committee on Organ Transplantation (ACOT) has been rechartered. The effective date of the renewed charter is August 31, 2018.

FOR FURTHER INFORMATION CONTACT: Robert Walsh, Executive Secretary, Advisory Committee on Organ Transplantation, Health Resources and Services Administration, Department of Health and Human Services, Room 08W60, 5600 Fishers Lane, Rockville, Maryland 20857. Phone: (301) 443–6839; fax: (301) 594–6095; email: *rwalsh@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The ACOT was authorized by section 121.12 of the amended Final Rule of the Organ Procurement and Transplantation Network (OPTN) (42 CFR part 121). In accordance with the Federal Advisory Committee Act (FACA), Public Law 92–463, it was initially chartered on September 1, 2000, and was renewed at the appropriate intervals.

The ACOT provides advice to the Secretary on all aspects of organ donation, procurement, allocation, and transplantation, and on such other matters that the Secretary determines. The recommendations of the ACOT will facilitate the Department's efforts to oversee the Organ Procurement and Transplantation Network (OPTN), as set forth in the National Organ Transplant Act of 1984, as amended.

The charter renewal for the ACOT was approved on August 31, 2018, which will also stand as the filing date. Renewal of the ACOT charter gives authorization for the Committee to operate until August 31, 2020.

A copy of the ACOT charter is available on the ACOT website at: *http://www.organdonor.gov/legislation/advisory.html.* A copy of the charter can also be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The website for the FACA database is *http://www.facadatabase.gov/.*

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–19454 Filed 9–6–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service (PHS) Funding is Sought and Responsible Prospective Contractors (Office of the Director)

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: Ms. Diane Dean, Director, Division of Grants Compliance and Oversight, Office of Policy for Extramural Research Administration, Office of Extramural Research, National Institutes of Health, 6705 Rockledge Drive, Room 3525, Bethesda, MD 20892, or call non-toll-free number (301) 435–0930 or Email your request, including your address to: *deand@od31em1.od.nih.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on March 16, 2018, (FR 83 pages 11763–11765) and allowed 60 days for public comment. One public comment was 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 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: Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service (PHS) Funding is Sought 42 CFR part 50 subpart F and Responsible Prospective Contractors 45 CFR part 94, 0925–0417, expiration date 2/28/2015, REINSTATEMENT WITHOUT CHANGE, Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research (OER), National Institutes of Health (NIH).

Need and Use of Information Collection: This request is for Office of Management and Budget (OMB) approval of a Reinstatement Without Change of a currently approved collection resulting from the development of revised regulations regarding the Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR part 50, subpart F) and Responsible Prospective Contractors (45 CFR part 94). The purpose of these regulations is to promote objectivity in research by requiring institutions to establish standards to ensure that there is no reasonable expectation that the design, conduct, or reporting of PHS-

funded research will be biased by any Investigator Financial Conflict of Interest (FCOI).

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 677,820.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents based on applicable section of regulation	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Reporting:				
Initial Reports under 42 CFR 50.605(b)(1) and (b)(3) or 45 CFR 94.5(b)(1) and (b)(3) from awardee Institutions.	992	1	2	1,984
Subsequent Reports under 42 CFR 50.605(a)(3)(iii) and (b)(2) or 45 CFR 94.5(a)(3)(iii) and (b)(2) from awardee Institutions.	50 FCOI reports as in 42 CFR 50.605(a)(3)(ii) and 45 CFR 94.5(a)(3)(ii).	1	2	100
	5 Mitigation Reports	1	2	10
Annual Report under 42 CFR 50.605(b)(4) or 45 CFR 94.5(b)(4) from awardee Institutions.	2,031	1	1	2,031
Subsequent Reports under 42 CFR 50.606(a) or 45 CFR 94.6 from awardee Institutions.	20	1	10	200
Record Keeping:				
Under 42 CFR 50.604(i) or 45 CFR 94.4(i) from awardee institutions.	2,000	1	4	8,000
Disclosure:				
Under 42 CFR 50.604(a) or 45 CFR 94.4 for Investigators.	3,000	1	81	243,000
Under 42 CFR 50.604(b) or 45 CFR 94.4(e)(1) for Investigators.	38,000	1	30/60	19,000
Under 42 CFR 50.604(b) or 45 CFR 94.4 (e)(1) for Institutions.	2,000	1	6	12,000
Under 42 CFR 50.604(c)(1) or 45 CFR 94.4(c)(1) from subrecipients.	500	1	1	500
Under 42 CFR 50.604(d) or 45 CFR 94.4 for Institutions.	3,000[1]	1	1	3,000
Under 42 CFR 50.604(e)(1) or 45 CFR 94.4(e)(1) for Investigators.	38,000	1	4	152,000
Under 42 CFR 50.604(e)(2) or 45 CFR 94.4(e)(2) for Investigators.	38,000	1	1	38,000
Under 42 CFR 50.604(e)(3) or 45 CFR 94.4(e)(3) for Investigators.	992	1	30/60	496
Under 42 CFR 50.604(f) or 45 CFR 94.4(f) for institutions.	2,000	1	1	2,000
Under 42 CFR 50.605(a)(1) or 45 CFR 94.5(a)(1) for Institutions.	2,000[2]	1	82	164,000
Under 42 CFR 50.605(a)(3) or 45 CFR 94.5(a)(3) for Institutions.	500[3]	1	3	1,500
Under 42 CFR 50.605(a)(3)(i) or 45 CFR 94.5(a)(3)(i).	50[4]	1	80	4,000
Under 42 CFR 50.605(a)(3)(ii) or 45 CFR 94.5(a)(3)(ii).	50[5]	1	80	4,000
Under 42 CFR 50.605(a)(3)(iii) or 45 CFR 94.5(a)(3)(iii).	50	1	1	50
Under 42 CFR 50.605(a)(4) or 45 CFR 94.5(a)(4)	992	1	12	11,904
Public Website Posting under 42 CFR 50.605(a)(5) or 45 CFR 94.5(a)(5) from awardee Institutions.	2,000	1	5	10,000
Under 42 CFR 50.606(c) or 45 CFR 94.6(c)	50[6]	[7]3	18/60	45
Total	136,282	136,382		677,820

[1] Assuming that 3,000 Institutions solicit disclosures on an annual basis by sending a notification to all Investigators.

[2] Although an estimated 992 reports of Conflict of Interest are expected annually, the 2,000 responding Institutions must review all financial disclosures associated with PHS-funded awards to determine whether any conflicts of interest exist. Thus, the review burden of 76,000 hours is based upon estimates that it will take on the average 2 hours for an institutional official(s) to review each of 38,000 financial disclosures associated with PHS funded awards. The burden for developing a management plan for identified FCOI is estimated at 80 hours × 992 cases = 79,360 hours.

[3] Assuming that this is a rare occurrence based on prior experience.

[4] Assuming only a fraction of the newly identified SFIs will constitute FCOI.

[5] Assuming only a fraction of the newly identified SFIs will constitute FCOI.

[6] Number based on 50.605/94.5(a)(3)(i)—of those only a fraction will relate to a project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, but we are calculating the maximum estimated burden.

[7] Assuming an average of 3 publications annually.

Dated: August 30, 2018.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2018–19339 Filed 9–6–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2018–0791]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0018

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0018, Official Logbook; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before November 6, 2018.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2108–0791] to the Coast Guard using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the internet at *http://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–612), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE, Stop 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2018–0791], and must be received by November 6, 2018.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Information Collection Request

Title: Official Logbook.

OMB Control Number: 1625–0018.

Summary: The Official Logbook contains information about the voyage, the vessel's crew, drills, watches, and operations conducted during the voyage. Official Logbook entries identify particulars of the voyage, including the name of the ship, official number, port of registry, tonnage, names and merchant mariner credential numbers of the master and crew, the nature of the voyage, and class of ship. In addition, it also contains entries for the vessel's drafts, maintenance of watertight integrity of the ship, drills and inspections, crew list and report of character, a summary of laws applicable to Official Logbooks, and miscellaneous entries.

Need: Title 46 U.S.C. 11301, 11302, 11303, and 11304 require applicable merchant vessels to maintain an Official Logbook. The Official Logbook contains information about the vessel, voyage, crew, and watch. Lack of these particulars would make it difficult for a seaman to verify vessel employment and wages, and for the Coast Guard to verify compliance with laws and regulations concerning vessel operations and safety procedures. The Official Logbook serves as an official record of recordable events transpiring at sea such as births, deaths, marriages, disciplinary actions, etc. Absent the Official Logbook, there would be no official civil record of these events. The courts accept log entries as proof that the logged event occurred. If this information was not collected, the Coast Guard's commercial vessel safety program would be negatively impacted, as there would be no official record of U.S. merchant vessel voyages. Similarly, those seeking to prove that an event required to be logged occurred would not have an official record available.

Forms: CG–706B, Official Logbook.

Respondents: Shipping companies.

Frequency: On occasion.

Hour Burden Estimate: The estimated annual burden remains at 1,750 hours a year.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: August 30, 2018.

James D. Roppel,

U.S. Coast Guard, Acting Chief, Office of Information Management.

[FR Doc. 2018–19412 Filed 9–6–18; 8:45 am]

BILLING CODE 9110–04–P