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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This draft guidance refers to previously approved collections of information found in FDA regulations.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-