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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Document Identifier: HHS-OS0990-new-60D

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Secretary, HHS

ACTION: Notice

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans to submit a new Information Collection Request (ICR), described below; to the Office of Management and Budget (OMB). Prior to submitting that ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit your comments to Information.CollectionClearance@hhs.gov or by calling (202) 690-6162.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, Information.CollectionClearance@hhs.gov or (202) 690-6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier HHS-OS-0990-New-60D for reference.

Comment Due 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.

Information Collection Request Title: Tissue and Organ Donor Epidemiology Study (TODES), OMB # 0990-New request, Office of the Assistant Secretary for Health.

Abstract: This Study is a request for a new data collection OMB Number: 0990-New TODES is being conducted in order to better understand the impact of donor screening and selection procedures, and to determine the extent of donor-donation level data that are collected for organ and tissue (including ocular) donors. The data that are obtained from Organ Procurement Organizations (OPOs) and Eye Banks will provide a better characterization of the deceased donor pool; information regarding data management and storage practices; and a measure of the degree of standardization of data collected by various organizations across the U.S. TODES may provide better estimates of the risk of HIV, HBV and HCV infections associated with organ and tissue transplantation and the potential for disease transmission; illustrate differences in laboratory screening methods and the impact of protocol variations; and serve as a pilot for future studies. This retrospective study will provide a framework for future, prospective studies of organ and tissue donors that could inform policy decisions regarding donor qualification procedures and, potentially, increase the donor pool.

A workshop in June 2005 (“Preventing Organ and Tissue Allograft-Transmitted Infection: Priorities for Public Health Intervention”) identified gaps in organ and tissue safety in the United States.¹ Participants developed a series of allograft safety initiatives, assessed progress, and identified priorities for future interventions. Despite progress, improved recognition and prevention of donor-derived transmission events is needed. It was concluded that this requires systems integration across the organ and tissue transplantation communities including organ procurement organizations, eye and tissue banks, and transplant infectious

disease experts. Commitment of resources and improved coordination of efforts are required to develop essential tools to enhance safety for transplant recipients.

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
OPOs	17	1	85/60	24.1
Eye Banks	7	1	55/60	6.4
Total				30.5

OS specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Darius Taylor

Information Collection Clearance Officer

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