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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: 0990-New-30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS

ACTION: Notice

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for a new collection. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit your comments to OIRA_submission@omb.eop.gov or via facsimile to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, Information.CollectionClearance@hhs.gov or (202) 690-5683.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the Information Collection Request Title and document identifier 0990-New-30D for reference.

Information Collection Request Title: National Tissue Recovery through Utilization Survey (NTRUS)

Abstract: The Office of the Assistant Secretary for Health, Department of Health and Human Services, is requesting OMB approval on a new ICR. This survey is being conducted to generate national estimates of recovery through utilization activity; of donated human tissue for calendar years 2012 and 2015, and to compare metrics across three data collection periods that includes results from a 2007 survey, the most recent year these data were collected. The survey and data collection and analysis methods will be similar to the 2007 survey. The general categories of information to be collected are listed under the Survey Section of the Annualized Burden Hour table below.

Need and Proposed Use of the Information: Policy advice provided by the HHS Advisory Committee on Blood and Tissue Safety and Availability to the HHS Secretary and Assistant Secretary for Health is used to direct departmental efforts to address transfusion and transplantation issues, such as emergency preparedness and infectious disease transmission related to donated human tissue. The advice provided is partly dependent on analysis of relevant information, such as tissue collection through utilizations data.

Likely Respondents: Respondents for this survey would be U.S. tissue banks that screen and recover tissue from living and deceased donors, and process, store, and/or distribute tissues grafts

for transplantation from these donors.

The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden Hours

Type of Respondent	Survey Section	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
All tissue banks	Tissue bank activities, tissue types handled, and inspections	110	1	10/60	18.33
Tissue banks that handle referrals, Recover/acquire tissue	Referrals, authorization, and informed consent; Tissue recovery and acquisition	80	1	1	80

Tissue banks that process tissue	Tissue processing	35	1	1	35
Tissue banks that store tissue	Tissue storage	65	1	20/60	21.67
Tissue banks that distribute tissue	Tissue distribution	58	1	30/60	29
Tissue banks that have donor infectious disease testing performed and may handle adverse outcome reports	Communicable disease testing and adverse outcome reports	35	1	1	35
Total					219

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