



Billing code: 4150-36-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: 0990-0278-30D]

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 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 renewal of the approved information collection assigned OMB control number 0990-0278, scheduled to expire on August 31, 2017. 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: Sherrette Funn, Sherrette.Funn@hhs.gov or

(202) 795-7714.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier 0990-0278-30D for reference.

Type of Collection Request: Extension of Currently Approved Collection

Title of the Collection: Federalwide Assurance Forms – Extension OMB No. 0990-0278,

Assistant Secretary for Health, Office for Human Research Protections.

Abstract: The Office for Human Research Protections is requesting a three year extension of the Federalwide Assurance (FWA). The FWA is designed to provide a simplified procedure for institutions engaged in HHS-conducted or supported research to satisfy the assurance requirements of Section 491(a) of the Public Health Service Act and HHS Regulations for the protection of human subjects at 45 CFR 46.103. The respondents are institutions engaged in human subjects research that is conducted or supported by HHS.

Affected Public: Individuals or households, business or other for-profit, not-for-profit institutions, Federal, State, Local, or Tribal Governments;

Estimated Annualized Burden in Hours Table

Form name	Number of Respondents	Number of Responses per Respondent	Hours per Response	Response Burden Hours
Federalwide Assurance (FWA)	14,000	2.0	0.50	14,000

Total				14,000
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Terry S. Clark,
Asst. Paperwork Reduction Act Clearance Officer.
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