



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier HHS-OS-0990-0278]

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 extension of the approved information collection assigned OMB control number 0990-0278, scheduled to expire on June 30, 2014. 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](mailto:OIRA_submission@omb.eop.gov) or via facsimile to (202) 395-5806.

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

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting

information, please include the OMB control number 0990-0278 and document identifier HHS-OS-0990-0278-30D for reference.

Information Collection Request Title: Federalwide Assurance Form, Assistant Secretary for Health, Office for Human Research Protections.

OMB No.: 0990-0278

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.

Need and Proposed Use of the Information: The information collected by OHRP through the FWA is the minimum necessary to satisfy the assurance requirements of the Public Health Service Act and the requirements of HHS regulations at 45 CFR 46.103.

Likely Respondents: Research institutions engaged in HHS-conducted or –supported research involving human subjects.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology

and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden - Hours

Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Federalwide Assurance (FWA)	11,050	2	30/60	11,050
Total				11,050

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Darius Taylor

Information Collection Clearance Officer

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