



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0278-30D]

### Agency Information Collection Request. 30-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

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

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain) . Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** Sherrette Funn, [Sherrette.Funn@hhs.gov](mailto:Sherrette.Funn@hhs.gov) or (202) 264-0041, or [PRA@HHS.GOV](mailto:PRA@HHS.GOV). When submitting comments or requesting information, please include the document identifier 0990-0278-30D and project title for reference.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (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.

Title of the Collection: Federalwide Assurance (FWA) Form

Type of Collection: Extension

Abstract: The Office of the Assistant Secretary for Health, Office for Human Research Protections (OHRP), is requesting a three-year extension of the OMB No. 0990-0278, Federalwide Assurance (FWA) Form, with no changes in the collected information. The purpose of the FWA form is to provide a simplified procedure for institutions engaged in research conducted or supported by the Department of Health and Human Services (HHS) to satisfy the assurance requirements of (1) Section 491(a) of the Public Health Service Act (the PHS Act) (42 U.S.C. 289); and (2) HHS regulations for the protection of human subjects at 45 CFR 46.103.

Type of Respondent: Institutions engaged in HHS-conducted or –supported research involving human subjects.

Estimated Annualized Burden Table

Type of Respondent	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Institutions engaged in HHS-conducted or –supported research involving human subjects.	14,000	2	30/60	14,000
<b>Total</b>				<b>14,000</b>

**Sherrette A. Funn,**

*Paperwork Reduction Act Reports Clearance Officer,*

*Office of the Secretary.*