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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: 0990-0278-60D]

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 an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for extending the use of the approved information collection assigned OMB control number 0990-0278, which expires on August 31, 2017. Prior to submitting the 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 and Sherrette.Funn@hhs.gov or by calling (202) 795-7714.

Information Collection Request Title: Federal-wide Assurance Forms

Abstract: Assistant Secretary for Health, Office for Human Research Protections is requesting Office of Management and Budget, OMB approval on a three year extension of the Federal-wide 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 subject research that is conducted or supported by HHS.

Need and Proposed Use of the Information: OHRP is the HHS component charged with fulfilling the statutory mandates of these provisions of the PHS Act and enforcing HHS regulations at 45 CFR part 46. The FWA provides a simplified assurance process that replaced the prior assurance mechanisms used by OHRP, all of which were more complicated and burdensome than the FWA. The information collected by OHRP through the FWA is the minimum necessary to satisfy the assurance requirements of the PHS Act and the requirements of HHS regulations at 45 CFR 46.103.

Likely Respondents: Individuals or households, business or other for-profit, not-for-profit institutions, Federal, State, Local, or Tribal Governments

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

Estimated Annualized Burden in Hours Table

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

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.

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