



DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0278]

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. 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: Natalie Klein, Natalie.Klein@hhs.gov or (240) 453-6900. When submitting comments or requesting information, please include the document identifier 0990-0278-30D and project title, Federalwide Assurance (FWA) Form, 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: Revision

OMB No. 0990-0278

Abstract: The Office of the Assistant Secretary for Health, Office for Human Research Protections (OHRP) is requesting a revision of the currently approved collection for the OMB No. 0990-0278, Federalwide Assurance (FWA) Form. The form is currently approved through October 31, 2026. 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. The respondents for this information collection are institutions engaged in HHS-conducted or –supported research involving human subjects. With this revision, OHRP is seeking to remove information from the FWA form to adopt the changes for assurances at 45 CFR 46.103 of the 2018 Requirements and reduce burden on respondents. The proposed changes to the FWA form include: 1) removing the Pre-2018 Common Rule requirement that institutions provide a statement of ethical principles; 2) removing the Pre-2018 Common Rule requirement that an institution designate one or more IRBs to review the research to which the FWA applies; 3) removing “check the box”, or the option for U.S. institutions to voluntarily apply the Common Rule, or the Common Rule and subparts B, C, and D of the HHS regulations at 45 CFR part 46, to all of an institution’s nonexempt human subjects research regardless of the source of support; and 4) eliminating the requirement for institutions outside the U.S. to provide procedural standards they apply for human subjects research when assuring compliance with the Terms of the Federalwide Assurance. Updates to the software applications OHRP uses to manage the FWA application process will be deployed to enable such changes.

Annualized Burden Hour Table:

Form name	Number of Respondents	Number of Responses per	Average Burden per	Total Burden Hours
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		Respondent	Response	
Federalwide Assurance (FWA)	13,000	1.0	0.33	4,290
Total				4,290

Catherine Howard,

Paperwork Reduction Act Reports Clearance Officer,

Office of the Secretary.

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