



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0263]

### Agency Information Collection Request; 60-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 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** Submit your comments to [Sherrette.Funn@hhs.gov](mailto:Sherrette.Funn@hhs.gov) or by calling (202) 264-0041 and [PRA@HHS.GOV](mailto:PRA@HHS.GOV).

**FOR FURTHER INFORMATION CONTACT:** When submitting comments or requesting information, please include the document identifier 0990-0263-60D and project title for reference, to Sherrette A. Funn, email: [Sherrette.Funn@hhs.gov](mailto:Sherrette.Funn@hhs.gov), [PRA@HHS.GOV](mailto:PRA@HHS.GOV) or call (202) 264-0041 the Reports Clearance Officer.

**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:* Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form.

*Type of Collection:* Renewal, three-year extension with non-substantive changes for the  
*Protection of Human Subjects:* Assurance Identification/IRB Certification/Declaration of  
Exemption Form OMB No. 0990-0263 Office of the Assistant Secretary for Health, Office for  
Human Research Protections

*Abstract:* The Office of the Assistant Secretary for Health, Office for Human Research  
Protections is requesting is requesting a three-year extension with non-substantive changes of the  
Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of  
Exemption Form, OMB No. 0990-0263.

The information collected on the form is to provide a simplified method for institutions engaged  
in research conducted or supported by the Department of Health and Human Services (HHS) to  
satisfy the requirements of HHS regulations for the protection of human subjects at 45 CFR  
46.103 for assurance identification and institutional review board (IRB) certification and declare  
exemption status. Non-substantive changes include adding instructions that, if additional  
assurances apply, those details can be indicated in the “Comments” section and clarifying that  
the form element for IRB expiration date does not apply to all projects.

*Likely Respondents:* Institutions engaged in research involving human subjects where the  
research is supported by HHS. Institutional use of the form is also relied upon by other Federal  
departments and agencies that have codified or follow the Federal Policy for the Protection of  
Human Subjects (Common Rule), which is codified for HHS at 45 CFR part 46, subpart A.

Annualized Burden Hour Table

<b>Form name</b>	<b>Number of Respondents</b>	<b>Number of Responses per Respondent</b>	<b>Hours per Response</b>	<b>Response Burden Hours</b>
Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption	13,000	2	0.5	13,000

**Sherrette A. Funn,**

*Paperwork Reduction Act Reports Clearance Officer,  
Office of the Secretary.*

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