



## 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) 795-7714.

**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 Funn, the Reports Clearance Officer, [Sherrette.funn@hhs.gov](mailto:Sherrette.funn@hhs.gov), or call 202-795-7714.

**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: Incident Report Form - the Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form.

Type of Collection:

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 a three-year extension of the Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form, OMB No. 0990-0263.

This form will facilitate prompt reporting of specific human subject protection incidents to OHRP by organizations and institutions conducting or reviewing human subjects research, and will provide a simplified standardized format for the reports. The information collected on the 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 requirements of HHS regulations for the protection of human subjects at 45 CFR 46.103 for assurance identification and IRB certification and declare exemption status.

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	14,000	2	0.5	14,000

Dated: January 12, 2021.

**Sherrette A. Funn,**

*Office of the Secretary,*

*Paperwork Reduction Act Reports Clearance Officer.*

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