



DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-new]

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: Sherrette Funn, Sherrette.Funn@hhs.gov or (202) 795-7714. When submitting comments or requesting information, please include the document identifier 0990-New-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: Incident Report Form

Type of Collection: New

OMB No. 0990-NEW- 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 approval for three years of a new information collection on the OHRP Incident Report Form. 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 will help OHRP to ensure the safety of human research subjects involved in non-exempt HHS-conducted or –supported research and to ensure that the research is conducted in accordance with the HHS Protection of Human Subjects regulations at 45 CFR part 46.

Likely Respondents: Institutions or organizations conducting non-exempt HHS-conducted or –supported human subjects research.

Annualized Burden Hour Table

Forms	Respondents	Responses per Respondent	Number of Responses	Hours per Response	Total Burden Hours
Incident Report Form	500	<u>1</u>	500	0.5	250
Incident Report Form	200	<u>2</u>	400	0.5	200

Incident Report Form	100	<u>3</u>	300	0.5	150
Total					600

Dated: January 12, 2021.

Sherrette A. Funn,

Office of the Secretary,

Paperwork Reduction Act Reports Clearance Officer.

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