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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-New-60D and project title for reference., to [Sherrette.funn@hhs.gov](mailto:Sherrette.funn@hhs.gov), or call 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. Information Collection Request Title: 0990-0263-Extension Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption (Common Rule) form.

Abstract: Assistant Secretary for Health, Office for Human Research Protections is requesting an extension on a currently approved information collection by the Office of Management and Budget, OMB, on the Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form. That form is designed 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. The respondents for this collection are 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 identical to 45 CFR part 46, subpart A.

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

ESTIMATE ANNUALIZED BURDEN IN HOURS TABLE

Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption	14,000	2	0.5	14,000
Total				14,000

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TERRY S. CLARK

Asst Information Collection Clearance Officer

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