4150-36-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier HHS-OS-0990-0263-30-D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice,

SUMMARY**:** In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for renewal of the approved information collection assigned OMB control number 0990-0263, scheduled to expire on March 31, 2015 Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit your comments to OIRA_submission@omb.eop.gov or via facsimile to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, Information.CollectionClearance@hhs.gov or (202) 690-6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting

information, please include the OMB control number 0990-0263 and document identifier HHS-OS-30D for reference.

Information Collection Request Title: Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form – Extension OMB No. 0990-0263, Assistant Secretary for Health, Office for Human Research Protections.

Abstract: The 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. That form is designed to promote uniformity among departments and agencies, and to help ensure common means of ascertaining institutional review board certifications and other reporting requirements relating to the protection of human subjects in research. The Federal Policy for the Protection of Human Subjects, known as the Common Rule, requires that before engaging in non-exempt human subjects research that is conducted or supported by a Common Rule department or agency, each institution must: (1) Hold an applicable assurance of compliance [Section 103(a)]; and (2) certify to the awarding department or agency that the application or proposal for research has been reviewed and approved by an IRB designated in the assurance [Sections 103(b) and (f)].

Need and Proposed Use of the Information: The information collected through the Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form is the minimum necessary to satisfy the assurance and certification requirements of Section 491 (a) of the Public Health Service Act and HHS Regulations for the protection of human subjects at 45 CFR 46.103.

Likely Respondents: Research institutions engaged in HHS-conducted or –supported research involving human subjects. 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).

Total Estimated Annualized Burden - Hours

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	12,000	2	30/60	12,000
Total				12,000

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Darius Taylor,

Information Collection Clearance Officer.

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