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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: HHS-0990-0279-60D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Assistant Secretary for Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary, Department of Health and Human Services (HHS), announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for extending the use of the approved information collection assigned OMB control number 0990-0279, which expires on August 31, 2015. Prior to submitting that ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

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 Information.CollectionClearance@hhs.gov or by calling (202) 690-6162.

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 document identifier 0990-0279 for reference.

Information Collection Request Title: Institutional Review Board Form – OMB No. 0990-0279, Assistant Secretary for Health, Office for Human Research Protections.

Abstract: Section 491(a) of Public Law 99-158 states that the Secretary of HHS shall by regulation require that each entity applying for HHS support (e.g., a grant, contract, or cooperative agreement) to conduct research involving human subjects submit to HHS assurances satisfactory to the Secretary that it has established an institutional review board (IRB) to review the research in order to ensure protection of the rights and welfare of the human research subjects. IRBs are boards, committees, or groups formally designated by an entity to review, approve, and have continuing oversight of research involving human subjects.

The Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) are requesting a three-year extension of the OMB No. 0990-0279, Institutional Review Board (IRB) Registration Form. This form was modified in 2009 to be consistent with IRB registration requirements, 45 CFR part 46, subpart E and 21 CFR 56.106 that were adopted in July 2009 OHRP and FDA, respectively.

Need and Proposed Use of the Information: The information collected through the Institutional Review Board registration collection requirements is the minimum necessary to satisfy the registration requirements of Section 491 (a) of the Public Health Service

Act, 45 CFR part 46, subpart E and 21 CFR 56.106.

Likely Respondents: Institutions or organizations operating IRBs that review human subjects research conducted or supported by HHS, or, in the case of FDA's regulations, IRBs in the United States that review clinical investigations regulated by FDA under sections 505(i) or 520(g) of the Federal Food, Drug and Cosmetic Act; and, IRBs in the United States that review clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products.

Burden Statement: The burden estimates for the IRB registration form include those approved by OMB in March 2015 under Control Number 0990-0263, the Assurance Identification/IRB Certification/Declaration of Exemption form (former Optional Form 310). Those burden estimates are not included as part of the burden estimate presented below.

Estimated Annualized Burden Table

Form name	Number of Respondents	Number of responses per respondent	Average burden per response (in hours)	Total Burden hours
IRB Registration 0990-0279	5,900	2	1	11,800
	500	2	1	1,000
Total				12,800

OS specifically requests comments on (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.

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