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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0260]
[30-day notice]

AGENCY: Office of the Secretary, HHS

Agency Information Collection Request. 30-Day Public Comment Request

In compliance with the requirement of section 3506(c)(2)(A) 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. 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.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to Sherette.funncoleman@hhs.gov, or call the Reports Clearance Office on (202) 690-5683. Send written comments and recommendations for the proposed information collections within 30 days of this notice directly to the OS OMB Desk Officer; faxed to OMB at 202-395-5806.

Proposed Project: Protection of Human Subjects: Assurance of Compliance with Federal Policy/IRB Review/IRB Recordkeeping/Informed Consent/Consent Documentation – OMB No. 0990-0260 - 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.

Pursuant to the requirement of the Public Law 99-158, HHS promulgated regulations at 45 CFR part 46, subpart A, the basic HHS Policy for the Protection of Human Subjects. The June 18, 1991 adoption of the common Federal Policy (56 FR 28003) by 15 departments and agencies implements a recommendation of the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research which was established on November 9, 1974, by Pub. L. 95-622. The Common Rule is based on HHS regulations at 45 CFR part 46, subpart A, the basic HHS Policy for the Protection of Human Subjects.

Total Estimated Annualized Burden - Dollars

Title	Number of	Number of	Average	Total
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	Respondents	responses per respondent	burden per response (in hours)	Burden hours
.103(b)(4), .109(d)IRB Actions, .116 and .117 Informed Consent	6,000	39.3 3	1	235,980
.115(a) IRB Recordkeeping	6,000	15	10	900,000
.103(b)(5) Incident Reporting, .113 Suspension or Termination Reporting	6,000	0.5	45/60	2,250
Total				1,138,230

Keith A. Tucker

Office of the Secretary

Paperwork Reduction Act Clearance Officer

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