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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: Subpart C Research Certification Form

Type of Collection: New

OMB No. 0990-NEW- Office within OS – Specific program collecting the data (is applicable)

Abstract: The Office for Human Research Protections (OHRP) is requesting a three year approval of the Department of Health and Human Services (HHS) Subpart C Research Certification Form. This form will facilitate the collection of information relevant to an institutional request for OHRP authorization of research involving prisoners; the information in the form will be entered into OHRP’s prisoner research database, and will be used by OHRP to draft a response certification letter back to the institution. This is a new information collection request.

The respondents for this collection are institutions or organizations operating Institutional Review Boards (IRBs) that have approved enrollment, or are planning to approve enrollment, of prisoners in human subjects research conducted or supported by HHS.

Estimated Annualized Burden Table

Type of Respondent	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Subpart C Certification Form	40	2	1	80
Total				80

Sherrette A, Funn,

Office of the Secretary,

Paperwork Reduction Act Reports Clearance Officer.

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