DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0279]

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 Natalie Klein, Natalie.Klein@hhs.gov and PRA@hhs.gov or by calling (240) 453-6900.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier "0990-0279-60D" and project title, "Department of Health and Human Services (HHS) Registration of an Institutional Review Board Form" for reference, to Natalie Klein, email: Natalie.Klein@hhs.gov, PRA@hhs.gov or by calling (240) 453-6900.

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: Department of Health and Human Services (HHS) Registration of an

Institutional Review Board Form.

Type of Collection: Revision

OMB No. 0990-0279

Abstract:

The Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) are requesting a revision of the currently approved collection for the Office of Management and Budget (OMB) No. 0990-0279, Department of Health and Human Services (HHS) Institutional Review Board (IRB) Registration Form. The revision request involves implementing a burden reducing change. Specifically, OHRP is seeking to remove the IRB roster membership information from the IRB registration form. This change will align the IRB registration form with the 2018 Requirements at 45 CFR 46.103. The change, when implemented, is anticipated to result in a shorter, simplified IRB registration process for respondents. Updates to the software applications OHRP uses to manage IRB registration will be deployed to enable such changes.

The current form is approved through June 30, 2025. The purpose of the form is to provide a simplified procedure for: (1) IRBs to satisfy the requirements for IRB registration at 45 CFR part 46, subpart E; and (2) IRBs in the United States (US) to satisfy the FDA requirements for IRB registration at 21 CFR 56.106.

Institutions engaged in nonexempt human subjects research conducted or supported by HHS, or another Common Rule department or agency, are required by the terms of the Federalwide Assurance (FWA) to rely upon only IRBs registered with OHRP for review of research to which the FWA applies, and must designate a registered IRB on the institution's FWA submission to OHRP. In this way, OHRP's FWA submission process, established pursuant to the requirements for assurances at 45 CFR 46.103, is linked to the regulatory requirements for IRB registration.

The respondents for this information collection are institutions or organizations operating

IRBs that review human subjects research conducted or supported by HHS; or, in the case of FDA's requirements, each IRB in the United States that reviews clinical investigations regulated by FDA under sections 505(i) or 520(g) of the Federal Food, Drug and Cosmetic Act; and each IRB in the United States that reviews clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products. Many of the IRBs also review research conducted or supported by other Common Rule departments and agencies.

Annualized Burden Hour Table

Form name	Number of Respondents	Number of responses per respondent	Average burden per response (in hours)	Total Burden hours
IRB Registration 0990-0279 Update and Renew	5,350	1	0.33	1,766
IRB-Registration 0990-0279 Initial and Update	350	2	0.5/0.33	291
Total				2,057

Susan R. Little,

Department Information Collection Clearance Officer,

Paperwork Reduction Act Program,

Department of Health and Human Services.

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