Agency Information Collection Request; 30-Day Public Comment Request

A Notice by the Health and Human Services Department on 07/20/2026

This document has a comment period that ends in 30 days. (08/19/2026)

PUBLISHED CONTENT - DOCUMENT DETAILS

Agency: Department of Health and Human Services
Agency/Docket Number: Document Identifier: OS-0990-0279
Document Citation: 91 FR 45279
Document Number: 2026-14537
Document Type: Notice
Pages: 45279-45280 (2 pages)
Publication Date: 07/20/2026

PUBLISHED DOCUMENT: 2026-14537 (91 FR 45279)

DOCUMENT HEADINGS

Department of Health and Human Services

[Document Identifier: OS-0990-0279]

AGENCY:

Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health (OASH), 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, submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. OMB will accept further comments from the public during the review and approval period.

DATES:

Comments on the ICR must be received on or before August 19, 2026.

ADDRESSES:

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice via *www.reginfo.gov/public/do/PRAMain (http://www.reginfo.gov/public/do/PRAMain)*. Find this information collection by selecting “Currently under Review” and “Select Agency: Department of Health and Human Services”.

FOR FURTHER INFORMATION CONTACT:

Natalie Klein, *Natalie.Klein@hhs.gov (mailto:Natalie.Klein@hhs.gov)* or (240) 453-6900. If requesting information, please include the document identifier 0990-0279-30D and project title (Department of Health and Human Services (HHS) Registration of an Institutional Review Board Form) 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: Department of Health and Human Services (HHS) Registration of an Institutional Review Board Form.

Type of Collection: Reinstatement with changes OMB No. 0990-0279.

Abstract: The Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) are requesting reinstatement with changes 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 previous information collection was approved by OMB on June 27, 2022, and expired on June 30, 2025. The request for reinstatement with changes involves implementing a burden reducing change. Specifically, OHRP is seeking to remove the IRB membership roster information collection from the IRB registration form. This change will align the IRB registration form with the 2018 Requirements at 45 CFR 46.103 (https://www.ecfr.gov/current/title-45/section-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 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 (https://www.ecfr.gov/current/title-45/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 (https://www.ecfr.gov/current/title-21/section-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.

In this way, OHRP's FWA process, established pursuant to the requirements for assurances at 45 CFR 46.103 (https://www.ecfr.gov/current/title-45/section-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	Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
IRB Registration Form 0990-0279	Institutions or Organizations that operate IRBs	5,350	1	0.5	2,675
Total		5,350	1	0.5	2,675

The estimate of the number of respondents is based upon the current number of IRBs registered with HHS, approximately 4,988 (as of July 13, 2026), and projecting that the number of respondents may increase to 5,350. Of the approximately 4,988 registered IRBs, 100% submitted their registration information electronically.

Of the 5,350 projected respondent IRBs, approximately 350 institutions or organizations are expected to submit IRB registration information for the first time, and nearly 5,000 institutions or organizations are expected to update or renew their existing IRB registration once each year. The burden is estimated to average 0.5 hours for both an initial IRB registration and for updating or renewing the registration of a previously registered IRB. If on average 5,000 (□ printed page 45280) previous respondents submit information once each year, and on average 350 submit new registration information one time a year, the total annual burden hours are projected to be 2,675 hours. Consistent with 5 CFR 1320.5(a)(1)(iv)(5) (https://www.ecfr.gov/current/title-5/section-1320.5#p-1320.5(a)(1)(iv)(5)), therefore, we believe this estimate represents the total annual reporting and recordkeeping burden that will result from the collection of information.

Catherine Howard,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2026-14537 (/d/2026-14537) Filed 7-17-26; 8:45 am]

BILLING CODE 4150-36-P

PUBLISHED DOCUMENT: 2026-14537 (91 FR 45279)