



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

**[Document Identifier: OS-0990-0481]**

### 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](http://www.reginfo.gov/public/do/PRAMain). Find this information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** Natalie Klein, [Natalie.Klein@hhs.gov](mailto:Natalie.Klein@hhs.gov) or (240) 453-6900. When submitting comments or requesting information, please include the document identifier 0990-0481-30D 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: For HHS/OASH Consultation Process, Institutional Review Board (IRB)

## Records

Type of Collection: Reinstatement without changes.

OMB No. 0990-0481

### Abstract:

The Office of the Assistant Secretary for Health (OASH), Office for Human Research Protections (OHRP) is requesting reinstatement of the Office of Management and Budget (OMB) information collection request, OMB No. 0990-0481, For OASH/HHS Consultation Process, Institutional Review Board (IRB) Records, with no changes, for a three-year period. The previous information collection was approved by OMB on February 14, 2022, and expired on February 28, 2025. The purpose of the collection is for OHRP to receive IRB records when an IRB or an institution requests an HHS consultation process for proposed research that is not otherwise approvable by an IRB involving, respectively: (1) pregnant women, human fetuses and neonates; (2) prisoners; or, (3) children, as subjects. The information that must be submitted to OHRP by an IRB or institution includes the research protocol, consent form, parental permission and child assent forms (if relevant), and other relevant IRB records (e.g., IRB minutes). The Office of the Assistant Secretary for Health, on behalf of the Secretary of HHS, may determine that such research can be conducted or supported by HHS after consulting with experts and meeting other procedural requirements.

*Likely Respondents:* IRBs

Annualized Burden Hour Table

45 CFR part 46 - HHS Consultation Process Provision	Respondent Type	No. of Respondents	No. of Respondents	Average Burden per Response (in hours)	Total Burden Hours
subpart B, §46. 207	IRBs	3	1	1	3
subpart C, §46.306(a)(2) (iii) and (iv)	IRBs	3	1	1	3
subpart D, §46.407	IRBs	4	1	1	4
TOTAL					10

**Susan R. Little,**

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*Paperwork Reduction Act Program,*

*Department of Health and Human Services.*

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