uncertainties about the strength of the available evidence on the clinical management (*e.g.,* dosage modifications, monitoring recommendations) of patients whose test results purport to identify partial DPD deficiency.

FDA is interested in obtaining public input on the above considerations and any other related aspects on which interested parties would like to comment. Specifically, FDA is interested in information on the following topics:

1. What, if any, challenges have healthcare providers and patients encountered based on the current recommendation to consider testing for genetic variants of DPYD prior to initiating treatment with fluorouracil or capecitabine to reduce the risk of serious adverse reactions if the patient's clinical status permits and based on clinical judgment?

2. What factors are considered by healthcare providers when deciding whether or not to test patients for DPD deficiency prior to initiating treatment with fluorouracil or capecitabine? Which, if any, of these factors may result in a healthcare provider's decision to initiate treatment with fluorouracil or capecitabine without prior testing for DPD deficiency?

3. What factors are considered by healthcare providers in deciding whether or not to use a fluorouracil or capecitabine product in a patient with a complete DPD deficiency (*e.g.,* using a markedly reduced dosage regimen) based on currently available data and information?

4. What factors are considered by healthcare providers for determining dosing and monitoring approaches when using a fluorouracil or capecitabine product in patients with purported partial DPD deficiency based on currently available data and information?

FDA will consider all suggestions, recommendations, and comments; however, the Agency will not respond directly to the person or organization making the suggestion, recommendation, or comment.

Dated: May 13, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–08960 Filed 5–19–25; 8:45 am]

BILLING CODE 4164–01–P

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 June 20, 2025.

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 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* 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	Number of respondents	Number 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,

Department Information Collection Clearance Officer, Paperwork Reduction Act Program, Department of Health and Human Services.

[FR Doc. 2025–09000 Filed 5–19–25; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Oncology 1—Basic Translational Integrated Review Group;Tumor Evolution, Heterogeneity and Metastasis Study Section.

Date: June 12–13, 2025.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Adriana Stoica, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, 7W234, Bethesda, MD 20892–9750, 240–276–6368, *Stoicaa2@mail.nih.gov.*

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Translational Immuno-oncology Study Section.

Date: June 16–17, 2025.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Maria Elena Cardenas-Corona, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817, 301–867–5309,*maria.cardenas-corona@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Health Services and Systems.

Date: June 16–17, 2025.

Time: 9:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Michael J McQuestion, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, Bethesda, MD 20892, 301–480–1276, *mike.mcquestion@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Topics in Neurodegeneration and Brain Injury.

Date: June 16–17, 2025.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Simonetta Camandola, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive Bethesda, MD 20892, (301) 480–3810, *sc288m@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cancer Therapeutics and Drug Development.

Date: June 16–17, 2025.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Lilia Topol, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6192, MSC 7804, Bethesda, MD 20892, 301–451–0131 *ltopol@mail.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Maximizing Investigators' Research Award A Study Section.

Date: June 16–17, 2025.

Time: 9:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Mollie Kim Manier, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–0510 *mollie.manier@nih.gov.*

Name of Committee: Oncology 1—Basic Translational Integrated Review Group; Cancer Genetics Study Section.

Date: June 16–17, 2025.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Juraj Bies, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4158, MSC 7806, Bethesda, MD 20892, 301–435–1256, *biesj@mail.nih.gov.*

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Biobehavioral Regulation, Learning and Ethology Study Section.

Date: June 16–17, 2025.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Sara Louise Hargrave, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 3170, Bethesda, MD 20892, (301) 443–7193, *hargravesl@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 14, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–08980 Filed 5–19–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Mentored Career Development Award Review.

Date: June 5, 2025.

Time: 4:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.