investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: March 23, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–06580 Filed 3–29–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Exemption of the Advanced Research Projects Agency for Health (ARPA–H) From Policies and Requirements of the National Institutes of Health (NIH)

AGENCY: Advanced Research Projects Agency for Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of the U.S. Department of Health and Human Services (HHS) has statutory authority to exempt the Advanced Research Projects Agency for Health (ARPA–H) from certain policies and requirements of the National Institutes of Health (NIH) as necessary and appropriate to ensure ARPA–H can most effectively achieve its statutorily specified goals. Pursuant to such authority, and for the reasons stated herein, the Secretary is giving notice that he intends to exempt ARPA–H from all NIH policies and requirements subject to the limitations and condition stated herein.

FOR FURTHER INFORMATION CONTACT: Thomas Libert, 240–731–3874, *tom.libert@arpa-h.gov.*

SUPPLEMENTARY INFORMATION: This notice follows 87 FR 32174, published on May 24, 2022. The Consolidated Appropriations Act, 2023 (Public Law 117–328, enacted on December 29, 2022) includes authorizing language for ARPA–H. Notably, section 499A of the Public Health Service Act (PHSA), as added by section 2331(a) of the Consolidated Appropriations Act, 2023, establishes ARPA–H within NIH and provides that the Director, ARPA–H, shall report to the Secretary of HHS.

Subparagraph (A) of section 499A(a)(3) provides that the Secretary may exempt ARPA–H from NIH policies and requirements that are in effect on the day before the enactment of section 499A as necessary and appropriate to ensure ARPA–H can most effectively achieve its statutorily specified goals, except as otherwise provided for in section 499A and subject to the requirements of subparagraph (B). Subparagraph (B) of section 499A(a)(3) provides that not later than 90 days after the date of enactment of section 499A, the Secretary shall publish a notice in the **Federal Register** describing the specific NIH policies and requirements from which the Secretary intends to exempt ARPA–H, including a rationale for such exemptions.

Pursuant to section 499A(a)(3) of the PHSA, notice is hereby given that I intend to exempt ARPA–H from all policies and requirements of the NIH that were in effect on the day before the enactment of section 499A, that is, on December 28, 2022.

The exemption is necessary and appropriate to ensure ARPA–H can most effectively achieve its statutorily specified goals and consistent with prior actions for the following reasons:

- The mission of ARPA–H is complementary to NIH, but its business model is distinct and separate. To succeed at its mission to realize transformative health solutions, ARPA–H must establish a unique culture and distinct and separate business and operations processes, including its own policies and requirements.
- On April 15, 2022, I transferred ARPA–H to NIH as authorized by title II of division H of the Consolidated Appropriations Act, 2022 (Pub. L. 117–103, enacted on March 15, 2022) and delegated to the Director, NIH, certain authorities for the purpose of carrying out ARPA–H (87 FR 23526). As a condition of the delegation, I specified that NIH may not subject ARPA–H to NIH policies.
- As noted, section 499A of the PHSA establishes ARPA–H within NIH and provides that the Director, ARPA–H, shall report to the Secretary. In the Joint Explanatory Statement (168 Cong. Rec. S8895, 2022), Congress signaled its intent for ARPA–H to establish its own culture, procedures, and policies:

> The agreement strongly encourages HHS to collaborate with the Defense Advanced Research Projects Agency (DARPA) to develop the foundational policies, procedures, and staff training for ARPA–H employees. The agreement believes ARPA–H will require a very different culture and mission than NIH's other 27 Institutes and Centers.

ARPA–H shall continue to be subject to all policies and requirements of HHS. All major policy, programmatic, and operational decisions proposed by ARPA–H shall continue to come to the Secretary for approval.

The exemption is subject to the following condition:

- Where ARPA–H identifies a need to develop a policy or requirement to fulfill its mission, it shall rely upon NIH policies and requirements until such time as ARPA–H develops its own policies and requirements as appropriate.

Xavier Becerra,

Secretary of Health and Human Services.

[FR Doc. 2023–06620 Filed 3–29–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) 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: Center for Scientific Review Special Emphasis Panel; Fellowships: Oncology.

Date: April 27, 2023.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Nywana Sizemore, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6189, MSC 7804, Bethesda, MD 20892, 301–408–9916, *sizemoren@csr.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: March 27, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–06639 Filed 3–29–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Application Process for Clinical Research Training and Medical Education at the Clinical Center and Its Impact on Course and Training Program Enrollment and Effectiveness

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institutes of Health Clinical Center (CC) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, contact: Tom Burklow, MD, Office of Clinical Research Training and Medical Education, NIH Clinical Center, National Institutes of Health, 10 Center Drive, Room 1N262, Bethesda, MD 20892–1158, or call non-toll-free number 301–435–8015, or email your request, including your address to: *tom.burklow@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimizes the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Application Process for Clinical Research Training and Medical Education at the NIH Clinical Center and Its impact on Course and Training Program Enrollment and Effectiveness, 0925–0698, REVISION, Exp., date August 31, 2023, National Institutes of Health Clinical Center (CC), National Institutes of Health (NIH).

Need and Use of Information Collection: The primary objective of the application process is to allow the Office of Clinical Research Training and Medical Education (OCRTME) at the NIH Clinical Center to evaluate applicants' qualifications to determine applicants' eligibility for training programs managed by the Office. Applicants must provide the required information requested in the respective applications to be considered a candidate for participation. Information submitted by candidates for training programs is reviewed initially by OCRTME administrative staff to establish eligibility for participation. Eligible candidates are then referred to the designated training program director/administrator or training program selection committee for review and decisions regarding acceptance for participation. Upon acceptance, OCRTME will collect required eligibility documents for respective training programs. A secondary objective of the application process is to track enrollment in training programs over time.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours 433.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Clinical Electives Program	Pre Doctoral Students	300	1	20/60	100
Graduate Medical Education	Physicians	100	1	20/60	33
Medical Research Scholars Program	Pre Doctoral Students	200	1	20/60	67
Resident Electives Program	Physicians	100	1	20/60	33
Bioethics Fellowship Program	Pre Doctoral, Post-Doctoral	300	1	20/60	100
OCRTME Onboarding Application	Pre Doctoral Students	300	1	20/60	100
Total			1,300		433

Dated: March 21, 2023.

Frederick D. Vorck, Jr.,

Project Clearance Liaison, NIH Clinical Center, National Institutes of Health.

[FR Doc. 2023–06641 Filed 3–29–23; 8:45 am]

BILLING CODE 4140–01–P