What mechanisms (*e.g.,* registries, electronic health records, post-approval studies) would best support timely, reliable postmarket data collection? *(Note: the pre-read document uses brain-computer interface (BCI) devices for amyotrophic lateral sclerosis (ALS) as a case example.)*

2. Under what clinical situations and statistical conditions can a single-arm device study with a performance goal or external control provide acceptable evidence of reasonable assurance of safety and effectiveness for devices for small patient populations—and what pre-specifications are needed to ensure such designs provide reliable and acceptable evidence? *(Note: the pre-read document uses BCI devices for ALS as a case example.)*

3. What design features would make an external data source appropriate for future pivotal studies in small populations? What infrastructure should be built proactively and by whom? *(Note: the pre-read document uses BCI devices for ALS as a case example.)*

4. What sources of prior information—feasibility studies, natural history data, international experience, prior device generations—are most appropriate and credible in small patient populations, and can hierarchical borrowing and Bayesian adaptive designs meaningfully improve efficiency and accelerate reliable evidence generation in this space?

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–18805 Filed 9–14–26; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, Optimization of the Health Services Workforce, October 08, 2026, 09:00 a.m. to October 09, 2026, 06:00 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on September 08, 2026, 91 FR 57156, Doc. No. 2026–18193.

This meeting is being amended to change the meeting from a 2-day to a 1-day meeting on October 8, 2026. The meeting is closed to the public.

Dated: September 11, 2026.

Rosalind M. Niamke,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–18874 Filed 9–14–26; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Oncology 2—Translational Clinical Integrated Review Group, Translational Immuno-oncology Study Section, October 15, 2026, 09:00 a.m. to October 16, 2026, 06:30 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on September 01, 2026, 91 FR 56151, Doc. No. 2026–17896.

This meeting is being amended to change the meeting from a 2-day to a 1-day meeting on October 15, 2026. And the start time to change from 9 a.m. to 8:30 a.m. The meeting is closed to the public.

Dated: September 10, 2026.

Rosalind M. Niamke,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–18825 Filed 9–14–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Engineered Cell Therapies for the Treatment of HPV 16 E6-Expressing Cancers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the patents and patent applications listed in the **SUPPLEMENTARY INFORMATION** section of this notice to MedGene Therapeutics, Inc. (''MedGene''), a company located in Silver Spring, Maryland, the United States of America.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before September 30, 2026 will be considered.

ADDRESSES: Inquiries and comments relating to the contemplated Exclusive Patent License should be directed to: Andrew Burke, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240) 276–5484; Email: *burkear@mail.nih.gov.*

SUPPLEMENTARY INFORMATION:

INTELLECTUAL PROPERTY

Reference No. (with country code)	Application No.	File date	Patent No.	Issue date
E–495–2013–0–US–01	61/846,167	7/15/2013		
E–495–2013–0–PCT–02	PCT/US2014/046480	7/14/2014		
E–495–2013–0–JP–07	2016–527006	1/15/2016	6628719	12/13/2019
E–495–2013–0–US–08	14/905,108	1/14/2016	9,822,162	11/21/2017
E–495–2013–0–US–09	15/786,966	10/18/2017	10,329,339	6/25/2019
E–495–2013–0–US–11	16/408,939	5/10/2019	10,913,785	2/9/2021
E–495–2013–0–JP–19	2019–219105	12/3/2019	6959970	10/12/2021
E–495–2013–0–US–22	17/142,486	1/6/2021	11,697,676	7/11/2023
E–495–2013–0–JP–23	2021–166407	10/8/2021	7223822	2/8/2023
E–495–2013–0–US–02	18/323,493	5/25/2023	12,187,779	1/7/2025