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

The prospective exclusive license territory may be ''Japan, Republic of Korea and the United States of America'', and the field of use may be limited to the following:

''Ex vivo generated T cell therapy products comprising autologous or allogeneic T cells genetically engineered to express exogenous T-cell receptors reactive to the HPV–16 E6 oncoprotein for the treatment of HPV-associated cervical cancer, head and neck cancer (including oropharyngeal cancer), and anogenital cancer in humans.''

The E–495–2013 patent family is primarily directed to an isolated T cell receptor (TCR) reactive to HPV 16 E6 antigen in the context of HLA–A*02. Among other applications, the claimed TCR may be useful in the development of engineered adoptive cell therapy products for the treatment of HPV–16 E6-positive cancers in patients who also express HLA–A*02.

Human papillomaviruses (HPV) are a diverse group of viral pathogens which commonly infect humans. While most infections are rapidly cleared by the host, certain HPV (*e.g.,* HPV 16 and 18) may establish chronic infections and are highly associated with the development of cancer. In such cases, cancer formation is facilitated by the sustained activity of certain oncoproteins, chiefly E5, E6 and E7.

E6 is a small (~150 amino acid) protein that promotes malignant transformation primarily through its ability to bind the tumor suppressor p53 in complex with the cellular ubiquitin ligase E6–AP (UBE3A), thereby targeting p53 for proteasomal degradation. Together with the E7 oncoprotein (which inactivates the tumor suppressor pRb), E6 cooperatively drives carcinogenesis in infected cells, and its continued expression is required for maintenance of the transformed phenotype. By virtue of this essential role and its restricted expression to diseased cells, E6 is a recognized therapeutic target.

The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Complete applications for a license that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

''This Notice is made in accordance with 35 U.S.C. 209(e) and 37 CFR 404 Authority to grant exclusive licenses.''

Dated: September 11, 2026.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2026–18877 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; 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: Center for Scientific Review Special Emphasis Panel; Institutional Research Training Programs in the Behavioral Health and Population.

Date: October 13–14, 2026.

Time: 10:00 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: Janetta Lun, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–4660, *janetta.lun@nih.gov*.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Therapeutic Development and Preclinical Studies Study Section.

Date: October 14–15, 2026.

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: Imoh Sunday Okon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817, (301) 451–1125, *imoh.okon@nih.gov*.

Name of Committee: Interdisciplinary Molecular Sciences and Training Integrated Review Group; Enabling Bioanalytical and Imaging Technologies Study Section.

Date: October 15–16, 2026.

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: Kenneth Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3218, MSC 7717, Bethesda, MD 20892, 301–435–0229, *kenneth.ryan@nih.gov*.

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Interdisciplinary Clinical Care in Specialty Care Settings Study Section.

Date: October 15–16, 2026.

Time: 9:30 a.m. to 5:30 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: Abu Saleh Mohammad Abdullah, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 827–4043, *abuabdullah.abdullah@nih.gov*.

Name of Committee: Infectious Diseases and Immunology A Integrated Review Group; Viral Pathogenesis and Immunity Study Section.

Date: October 15–16, 2026.

Time: 10:00 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: Neerja Kaushik-Basu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3198, MSC 7808, Bethesda, MD 20892, (301) 435–1742, *kaushikbasun@csr.nih.gov*.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Social and Environmental Determinants of Health Study Section.

Date: October 15–16, 2026.

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

Agenda: To review and evaluate grant applications.