Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Cicely Reese; Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3215, Silver Spring, MD 20993–0002, 301–796–9025, email: *CBERCTGTAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. On July 30, 2026, the Committee will meet in open session to discuss and make recommendations on Biologics License Application (BLA) 125827, from Replimune, Inc. for vusolimogene oderparepvec. The proposed indication (use) is in combination with nivolumab for the treatment of adult patients with advanced melanoma who have previously received an anti-PD–1 containing regimen.

FDA intends to make background material available to the public no later than two (2) business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference and/or video conference meeting will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before July 20, 2026, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately 1:05 p.m. and 2:05 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, along with the names, email addresses, and direct contact phone numbers of proposed participants, and an indication of the approximate time requested to make their presentation on or before 12 p.m. Eastern Time on July 15, 2026. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by 6 p.m. Eastern Time on July 17, 2026.

For press inquiries, please contact the HHS Press Room at *www.hhs.gov/press-room/index.html* or 202–690–6343. FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Cicely Reese at *CBERCTGTAC@fda.hhs.gov* (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–13810 Filed 7–7–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request: Generic Clearance for the Collection of Customer Participation and Performance Management With NIH Programs, Products, and Services (Office of the Director)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide an opportunity for public comment on proposed data collection projects, the National Institutes of Health, National Cancer Institute (NCI) 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 by August 7, 2026.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Diane Kreinbrink, Program Manager, Office of Management Policy and Compliance, National Cancer Institute, 9609 Medical Center Drive, Room 2W446, Bethesda, Maryland 20892 or call non-toll-free number (240) 276–7283 or email your request, including your address to: *diane.kreinbrink@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: Generic Clearance for the Collection of Customer Participation and Performance Management with NIH Programs, Products, and Services (NIH), 0925–0778: Expiration Date 9/30/2026, Extension, National Institutes of Health (NIH).

Need and Use of Information Collection: Evaluating the effectiveness of leadership, programs, and services is essential for the vitality of any institution. Leadership review at NIH focuses on the productivity of the IC, management of resources and budget allocations, training activities, and influence on dimensions of diversity, inclusion, promotion of investigators and staff (including NIH Equity Committee (NEC) reports), and positive workforce culture.

Program and service reviews may focus on operational performance; outputs, outcomes, and impacts; policy compliance, stewardship, diversity, equity, and inclusion. Both types of reviews and evaluations may solicit input from IC staff and leadership (IC Director, Deputy Director, E.O.) and relevant program participants and stakeholders about the program's effectiveness, leader, or process. They may include comparisons with other ICs or programs, external benchmarks, and outcome metrics where appropriate and applicable. This input should provide meaningful information that can be used to identify strengths and areas that need improvement. Reports developed from the review or evaluation may be presented by the IC Director to the IC's Advisory Council or Board, to other IC or NIH leadership (such as the Deputy Director for Intramural Research and the NIH Director), or to program participants or the broader public. Such reports may include recommendations and proposed actions to address areas for improvement. In public or broadly shared reports, any sensitive information in the reviews or evaluations will be summarized and presented in aggregate.

This clearance will allow direct assessment and measurement of the customer/respondent base for participation in and satisfaction with NIH programs, products, and services. The clearance will also enable offices to assess participants' experience and accomplishments during or since participation and their preferences for existing and future programming, products, and services. The information collected using these tools informs and supports budgeting, program management and design, program planning, results reporting, information dissemination, and outreach initiatives.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 3,375.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hour
Individuals, Households, Private Sector, State Government, Local Government, Tribal Government, or Federal Government.	Performance Measurement	500	1	30/60	250
	Interviews	1,000	1	1	1,000
	Program Reviews	500	1	45/60	375
	Surveys	5,000	1	15/60	1,250
	Focus Groups	500	1	1	500
Totals			7,500		3,375

The Deputy Director for Extramural Research, Jon Lorsch, having reviewed and approved this document, authorizes Alycia Booth, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: July 6, 2026.

Alycia Booth,

Federal Register Liaison, National Institutes of Health.

[FR Doc. 2026–13806 File 7–7–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Invention Available for License: Generating Conditional and Reverse Conditional Loss-of-Function Alleles in Mouse Casq2

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) is seeking potential licensees interested in further developing or utilizing these Casq2 mouse strains. As a research tool, patent protection is not being pursued for this technology. More information to access these strains can be found here: *https://www.jax.org/strain/036291* and *https://www.jax.org/strain/036290.*

FOR FURTHER INFORMATION CONTACT: Inquiries related to this license opportunity should be directed to: Heather Gunas JD, MPH, Senior Technology Transfer Manager, NCI, Technology Transfer Center, Email: *gunash@mail.nih.gov* or Phone: 240–276–5530.

SUPPLEMENTARY INFORMATION: Cardiac calsequestrin (Casq2) plays an essential role in maintaining cardiac Ca^{2+} homeostasis. Human *CASQ2* mutations are associated with catecholaminergic polymorphic ventricular tachycardia (CPVT), a rare familial arrhythmogenic disorder within a group of diseases characterized as Sudden Arrhythmic Death.

The inventors have generated Casq2Flox and Casq2RevFlox mouse strains that model CPVT. The two novel strains successfully phenocopy aspects of CPVT, including stress-induced arrhythmias and reduced basal heart rates. The strains allow investigators to determine the importance of Casq2 gene function in specific tissues and at specific developmental time points. They also allow investigators to determine the efficacy of gene therapy and to address key mechanism questions. The materials are validated and fully functional.

This Notice is in accordance with 37 CFR 404.4 Authority to grant licenses.

NIH Reference Number: E–128–2024.

Related Technologies: N/A.

Product Type: Research Material/Tool.

Therapeutic Area(s): Rare/Neglected Disease.

Development Stage: Validated and fully functional.

Publications:

- Knollmann BC, et al. *Casq2* deletion causes sarcoplasmic reticulum volume increase, premature Ca^{2+} release, and catecholaminergic polymorphic ventricular tachycardia. (PMID 16932808).
- Flores DJ, et al. Conditional ablation and conditional rescue models for Casq2 elucidate the role of development and of cell-type specific expression of Casq2 in the CPVT2 phenotype. (PMID 29452352).
- Blackwell DJ, et al. The Purkinje–myocardial junction is the anatomic origin of ventricular arrhythmia in CPVT. (*PMID* 34990403).

Patents: N/A.

Potential Commercial Applications:

- Study of Casq2 function.
- Study of calcium storage in cardiac muscle and CPVT.
- Determining the efficacy of gene therapy for CPVT pies.

Competitive Advantages:

- Only available conditional and reverse conditional loss-of-function alleles in mouse Casq2.
- Allows the study of Casq2 gene function in specific tissues and at specific developmental points.

Collaboration Opportunity: NICHD seeks licensing for further developing or utilizing these Casq2 mouse strains.

Dated: July 6, 2026.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2026–13802 Filed 7–7–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Invention Available for License: Method of Detecting Circulating Cell-Free HPV 6 and 11 DNA in Patients Afflicted With Diseases Caused by Chronic HPV 6 or 11 Infection and Use Thereof

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI) and Frederick National Laboratory for Cancer Research (FNLCR) seek research co-development partners and/or licensees for commercial development of a novel liquid biopsy diagnostic for non-invasive detection of cell-free HPV 6 and 11 DNA for recurrent respiratory papillomatosis (RRP).

FOR FURTHER INFORMATION CONTACT: Inquiries related to this license opportunity should be directed to: Suna Gulay French, Ph.D., Technology Transfer Manager, NCI, Technology Transfer Center, Email: *suna.gulay@nih.gov* or Phone: 240–276–7424.

SUPPLEMENTARY INFORMATION: RRP, caused by chronic infection with human papillomavirus (HPV) types 6 and 11, is a rare but potentially fatal disease characterized by the growth of papillomas throughout the respiratory tract. While HPV 6/11 infections are common, affecting approximately 40% of U.S. adults, a subset of patients can develop a range of conditions from benign papillomas to dysplasia and invasive cancers. Current treatment for RRP typically involves repetitive surgical intervention or laser ablation to alleviate symptoms, which carries significant procedural risks. A recent breakthrough with a therapeutic HPV vaccine demonstrated that 51% of patients avoided surgery for at least a year, with some experiencing durable remission. However, there remains no reliable diagnostic tool to confirm viral clearance or guide systemic therapy decisions.

Researchers at the NCI and FNLCR have developed a novel hybridization-based next-generation sequencing (NGS) liquid biopsy method to detect circulating cell-free HPV 6 and 11 DNA in the plasma of patients with RRP. This innovative approach uses the established relevance of circulating viral DNA as a valuable biomarker for disease monitoring and therapeutic decision-making in other virally-associated conditions. The method is designed to target multiple regions across the entire HPV 6 and 11 genomes. It employs a pull-down DNA technology to enhance coverage—overcoming limitations of fixed-primer PCR for small cell-free DNA fragments. While low-risk HPV-associated diseases like RRP exhibit less tumor cell turnover compared to advanced cancers, the inherent high vascularity of papillomas may facilitate the release of viral DNA into peripheral blood. This method offers a non-invasive, sensitive and potentially prognostic tool to aid in (1) diagnosis, (2) monitoring progression and (3) guiding systemic therapies such as HPV vaccination or predicting severity—including pulmonary risk.