international health bodies of peer regulatory bodies?

6. If new categories were adopted, what is needed to preserve access to vaccines currently available to Americans and ensure predictable and consistent treatment under coverage requirements, program eligibility rules, the injury-compensation programs, and State law?

7. If categories remain the same, what modifications to timing and frequency of vaccine administration (for example, clearer presentation of flexible age ranges such as the 12-through-15-month window for the first dose of measles-containing vaccine) or guidance on administering vaccines individually versus at a single visit would help parents and clinicians understand that a vaccine is recommended while affording flexibility in timing of administration?

C. Shared Clinical Decision-Making: Meaning, Risks, and Benefits

8. What does, or what should, ''shared clinical decision-making'' mean in the vaccination context? How, if at all, does ''individual-based decision-making'' differ?

9. Does the term ''shared clinical decision-making'' create an unintended contrast with routine recommendations? Since shared decision-making describes a clinical process applicable to all vaccine decisions, should the Department reserve that phrase for use across all categories and instead adopt ''conditional recommendation'' or ''recommendation based on individualized assessment'' for recommendations whose expected benefit varies materially among individuals?

10. What are the benefits of an SCDM category, including respect for autonomy, informed consent, religious conviction, and individualized clinical judgment, and what evidence supports them?

11. What are the risks of an SCDM category, including confusion, reduced access or uptake, and time burdens in practice, and what evidence supports them?

12. An SCDM recommendation, once adopted by the CDC Director, triggers the same coverage requirements as a routine recommendation, including coverage without cost-sharing under the Affordable Care Act and availability through the Vaccines for Children program. Given evidence that patients and even providers may not understand this, what steps should the Department take to educate the public and the provider community that SCDM-recommended vaccines are covered? What communication formats would most effectively ensure that an SCDM designation is not misread as a lapse in coverage or a signal that a vaccine is unavailable?

13. What supports would make SCDM work as intended, such as decision aids, provider training, documentation standards, coverage clarifications, or category-specific communication materials, and who should develop them?

D. Considerations in Setting Recommendations

14. What considerations should be relied upon in establishing vaccine recommendations and assigning categories, and under what conditions should each predominate? Commenters are specifically invited to address the availability, quality, and strength of evidence; the appropriate approach where randomized controlled trial evidence is absent, infeasible, or unethical to obtain; disease severity and epidemiology; individual versus population benefit; a presumption in favor of individual autonomy, informed consent, and religious freedom; and feasibility and programmatic consequences.

15. When evidence is limited, uncertain, or evolving, how should that uncertainty be reflected in the recommendation itself, whether through category assignment, qualifying language, sunset or re-review provisions, or explicit statements of evidentiary certainty, rather than resolved silently in favor of either a universal recommendation or no recommendation?

E. Trust and Communication

16. What does the evidence show about the effects of mandates and other compulsory or high-pressure approaches on public trust, vaccine confidence, and long-run vaccination behavior? How should Federal recommendation policy account for those effects, consistent with the principle that Federal recommendations are not mandates?

17. What communication practices should accompany vaccine recommendations so that they earn and keep public trust, and what lessons from COVID–19-era communication should inform them?

18. How should the Department measure whether a recommendation framework is succeeding, and what data should be collected and published for that purpose?

III. Scope and Effect of This Notice

This request for information does not constitute a rule, a proposed rule, or a recommendation, and it does not alter any existing vaccine recommendation, coverage requirement, or program obligation. The Department will not respond individually to comments but will consider them in the work described above.

Robert F. Kennedy, Jr.,

Secretary, U.S. Department of Health and Human Services.

[FR Doc. 2026–17250 Filed 8–21–26; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Invention Available for License: T Cell Receptors Targeting HPV 6 or HPV 11

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI) seeks research co-development partners and/or licensees for a collection of T cell receptors (TCRs) that specifically target HPV 6 or HPV 11 antigens.

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: Recurrent Respiratory Papillomatosis (RRP) and anogenital condyloma arise from chronic infection with human papillomavirus (HPV) 6 or 11. They can cause significant morbidity due to persistent papillomatous growths in the upper aerodigestive or anogenital tract. In RRP, lesions may obstruct the airway (leading to dysphonia), dyspnea, recurrent pneumonia, or pulmonary failure. In rare cases, it may progress to malignancy. Current treatment options for RRP include zopapogene imadenovec (Papzimeos), systemic bevacizumab, and repeated surgical debulking. Papzimeos can lead to durable responses in some patients but remains ineffective against pulmonary disease. Systemic bevacizumab can control disease, but prolonged use can lead to intolerable toxicities. Repeat surgical debulking causes cumulative surgical and anesthetic risks. Therefore, there remains a critical unmet need for

safe and effective therapies for patients with aggressive or pulmonary RRP refractive to standard-of-care treatments.

Researchers at the NCI identified several T cell receptors (TCRs) with potential utility in adoptive cell therapy and other TCR-based approaches to treat HPV 6- or HPV 11-associated diseases—including RRP. These TCRs used engineered T cells derived from peripheral blood mononuclear cells (PBMCs), an easily accessible source of human immune cells. The engineered T cells demonstrated reproducible, antigen-specific recognition of multiple HPV 6 and HPV 11 proteins presented by diverse HLA class I subtypes. The inventors further showed that these TCR-engineered T cells effectively eliminated HPV 6/11-infected target cells. Such results support the therapeutic potential of these TCRs for HPV-associated disease. The intellectual property rights have been assigned to the Government of the United States of America.

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

NIH Reference Number: E–002–2026–0.

Related Technologies: E–143–2024–0 and E–019–2025–0.

Product Type: Therapeutic.

Therapeutic Area(s): Immunology | Infectious Disease | Oncology.

Development Stage: Pre-clinical (*in vivo* validation).

Publications: N/A.

Patent(s): Provisional patent application.

Potential Commercial Applications:

- Treatment and diagnosis of recurrent RRP and other premalignant and nonmalignant conditions.
  - Adoptive cell therapy.
  - TCR-based therapy.
  - Combination therapy.
- Treatment and diagnosis of additional HPV 6- or HPV 11-associated diseases and chronic infections.
  - Adoptive cell therapy.
  - TCR-based therapy.
  - Combination therapy.

Competitive Advantages:

- Novel adoptive cell therapies, either as monotherapies or in combination with other therapeutic modalities.
- Promising freedom to practice as part of a comprehensive intellectual property portfolio for RRP therapeutics and diagnostics.
- Established FDA regulatory precedent for TCR-based therapeutics.
- Opportunity to qualify for regulatory incentives for rare diseases, including: orphan drug designation, priority review, and breakthrough therapy designation.

Collaboration Opportunity: Researchers at the NCI seek licensing and/or co-development research collaborations for a collection of T-cell receptors (TCRs) that specifically target HPV 6 or HPV 11 antigens.

Dated: August 19, 2026.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2026–17188 Filed 8–21–26; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2026–0041]

Notice of Availability and Request for Comments on Draft Navigation and Vessel Inspection Circular 02–99 Change 1—Guidance on the Streamlined Inspection Program

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability and request for comments.

SUMMARY: The Coast Guard announces the availability of draft Navigation and Vessel Inspection Circular (NVIC) 02–99, Change 1, Guidance on the Streamlined Inspection Program. NVIC 02–99, Change 1 would modernize the program guidance to reflect industry advancements in digital recordkeeping, maintenance management systems, and third-party auditing. This update would emphasize a risk-based verification model that reduces redundant physical inspections, broadens acceptable compliance formats, and provides updated procedures for deficiency management and temporary hull repairs.

DATES: Comments must be submitted to the online docket via *https://www.regulations.gov* on or before September 23, 2026.

ADDRESSES: You may submit comments identified by docket number USCG–2026–0041 at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: For information about this document call or email LCDR Samuel Rodriguez, Coast Guard; telephone 571–608–7959, email *Samuel.Rodriguez-Gonzalez@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Public Participation and Comments

We encourage you to submit comments (or related material) on the draft NVIC 02–99, Change 1 Guidance on the Streamlined Inspection Program. We will consider all submissions provided by the deadline and may adjust our final action based on your comments. If you submit a comment, please include the docket number for this notice, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments at *http://www.regulations.gov.* To do so, go to *https://www.regulations.gov,* type USCG–2026–0041 in the search box and click ''Search.'' Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Viewing material in docket. To view documents mentioned in this notice as being available in the docket, find the docket as described in the previous paragraph, and then select ''Supporting & Related Material'' in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the *https://www.regulations.gov* Frequently Asked Questions web page.

Personal information. We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided, except that contact information (such as email or mailing address) will not be available for public viewing, unless the submitter includes that information in the body of the docket submission. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Discussion

The Coast Guard is making available for comment a draft Change 1 to NVIC 02–99, Guidance on the Streamlined Inspection Program. Originally published in 1999, the Streamlined Inspection Program (SIP) provides an alternative, company-managed process for ensuring compliance with vessel inspection regulations. Since its inception, the maritime industry has modernized, increasingly relying on digital compliance systems, robust safety management systems, and third-party audits.

This updated draft guidance would modernize the SIP to align with these industry advancements. The draft NVIC