

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form No.	Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours *
143	Adult Heart and HeartLung Status 4 Exception Extension Justification Form Medical Urgency Data.	149	2.17	323	0.25	80.83
144	Adult Heart and HeartLung Status 4 Criteria 2 Extension Justification Form Medical Urgency Data.	149	0.78	116	0.4	46.49
145	Adult and Pediatric Lung and HeartLung Goal Exception Form.	149	2.785	415	0.75	311.22
146	Pediatric Lung Priority 1 Status Justification Form	45	0.53	24	0.33	7.87
147	Review Board Voter Form	251	24.745	6,211	0.23	1,428.53
148	Living Donor Feedback Form	209	38.856	8,121	0.13	1,055.72
149	Extra Vessels Reporting Form	251	59.28	14,879	0.03	446.38
150	Non-US Transplants Reporting Form ***	232	0.00	0	0.03	0.00
151	Discrepant HLA Typings Reporting Form	137	1.27	174	5.17	899.53
152	Interim Event Reporting Form	251	88.454	22,202	0.06	1,332.12
153	Patient Safety Contact Management Form **	306	42.20	12,913	0.14	1,807.85
154	Patient Transfer Form **	251	15.35	3,853	0.39	1,502.61
	Total	19,424	3,101,339	910,553.02

* **Note:** Totals for responses and burden hours may reflect minor discrepancies due to rounding; however, these rounding adjustments do not affect the overall burden estimates presented.

** New forms.

*** If a form has 0.00 under the average number of responses, this is an indicator that there were no submissions in calendar year 2025.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2026-09804 Filed 5-14-26; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Inventions Available for License: Synergistic Interactions for Improved Cancer Treatment

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI) seeks research co-development partners and/or licensees to develop hetIL-15 in combination with other agents, such as PPARa agonists (Fenofibrate), FLT3 inhibitors (quizartinib), IL-12, or chemotherapy into a therapeutic for cancer.

FOR FURTHER INFORMATION CONTACT:

Inquiries related to this license opportunity should be directed to: Rose Freel, Ph.D., Unit Supervisor, NCI, Technology Transfer Center, Email: rose.freel@nih.gov or Phone: 301-624-1257.

SUPPLEMENTARY INFORMATION:

Immunotherapy has emerged as a promising treatment strategy for many types of cancer. However, a major challenge is "exhausted" tumor-infiltrating immune cells, which lose their ability to effectively eliminate cancer cells. To address this issue, researchers are exploring ways to reverse immune exhaustion and improve treatment outcomes. One potential approach involves interleukin-15 (IL-15), a cytokine that promotes the growth and killing ability of tumor-specific CD8+ T cells and NK cells. IL-15, either alone or in combination with other agents, has shown some promise in clinical trials. However, its use is hindered by toxicity at effective doses. Therefore, there is a critical need for safer and more effective combinations to improve patient outcomes.

Inventors at the NCI previously developed heterodimeric IL-15 (hetIL-15), composed of IL-15 and IL-15 receptor alpha (NIH Reference #E-254-2005, E-257-2009, E-141-2008, E-054-2013, and E-070-2015). The inventors now demonstrate novel combinations of hetIL-15 with other active agents to enhance the metabolic fitness of intratumoral lymphocytes to provide therapeutic improvement. Specifically, the combination of hetIL-15 and

Fenofibrate, a cholesterol-lowering drug, increased cytotoxic T cell activity and provided an almost complete eradication of triple negative breast cancer tumors, including metastatic lesions. Similar results occurred in a mouse pancreatic cancer model. Using a mouse orthotopic breast cancer model, hetIL-15 combined with quizartinib—a potent Fms-like tyrosine kinase 3 (Flt3) inhibitor—resulted in a significant tumor growth delay and complete eradication of tumors in 50% of mice after 16 days of treatment. Additionally, the inventors constructed a fusion protein of IL-15 and IL-12 that controls metastatic disease in a mouse melanoma model. These novel combinations would be particularly useful for the treatment of triple negative breast or pancreatic cancer.

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

NIH Reference Number: E-174-2022.

Product Type: Therapeutic.

Therapeutic Area(s): Oncology | Immunology.

Potential Commercial Applications:

- Treatment for triple negative breast cancer.
 - Treatment for pancreatic cancer.
 - Treatment of solid tumors for which cellular immunotherapy outcomes are diminished due to T or NK cell exhaustion.
 - Treatment of solid tumors for which IL-15-based therapy is diminished due to toxicity at clinically relevant doses.
- Competitive Advantages:
- Novel combination showing improved therapeutic potential in

several solid cancers, including breast cancer and melanoma.

- Combination of hetIL-15 with agents already approved (Fenofibrate, Flt-3) decreases regulatory risk and thus expedites commercialization.

- Overcoming IL-15 toxicity at clinically relevant doses.

Dated: May 13, 2026.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2026-09808 Filed 5-14-26; 8:45 am]

BILLING CODE 4167-05-P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

Determination Pursuant to Section 102 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, as Amended

AGENCY: Office of the Secretary, Department of Homeland Security.

ACTION: Notice of determination.

SUMMARY: The Secretary of Homeland Security has determined, pursuant to law, that it is necessary to waive certain laws, regulations, and other legal requirements in order to ensure the expeditious construction of barriers and roads in the vicinity of the international land border in the state of Texas.

DATES: This determination takes effect on May 15, 2026.

SUPPLEMENTARY INFORMATION: Important mission requirements of the Department of Homeland Security (“DHS”) include border security and the detection and prevention of illegal entry into the United States. Border security is critical to the nation’s national security. Recognizing the critical importance of border security, Congress has mandated DHS to achieve and maintain operational control of the international land border. Secure Fence Act of 2006, Public Law 109–367, section 2, 120 Stat. 2638 (Oct. 26, 2006) (8 U.S.C. 1701 note). Congress defined “operational control” as the prevention of all unlawful entries into the United States, including entries by terrorists, other unlawful aliens, instruments of terrorism, narcotics, and other contraband. *Id.* Consistent with that mandate, the President’s Executive Order on Securing Our Borders directs that I take all appropriate action to deploy and construct physical barriers to ensure complete operational control of the southern border of the United States. Executive Order 14165, section 3 (Jan. 20, 2025).

Congress has provided to the Secretary of Homeland Security a number of authorities necessary to carry out DHS’s border security mission. One of those authorities is found at section 102 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, as amended (“IIRIRA”). Public Law 104–208, Div. C, Tit. I, section 102, 110 Stat. 3009–546, 3009–554 (8 U.S.C. 1103 note), as amended by the REAL ID Act of 2005, Public Law 109–13, Div. B, Tit. I, section 102, 119 Stat. 302, 306 (8 U.S.C. 1103 note), as amended by the Secure Fence Act of 2006, Public Law 109–367, section 3, 120 Stat. 2638 (8 U.S.C. 1103 note), as amended by the Department of Homeland Security Appropriations Act, 2008, Public Law 110–161, Div. E, Tit. V, section 564, 121 Stat. 2042, 2090. In section 102(a) of IIRIRA, Congress provided that the Secretary of Homeland Security shall take such actions as may be necessary to install additional physical barriers and roads (including the removal of obstacles to detection of illegal entrants) in the vicinity of the United States border to deter illegal crossings in areas of high illegal entry into the United States. In section 102(b) of IIRIRA, Congress mandated that in carrying out the authority of section 102(a), I provide for the installation of additional fencing, barriers, roads, lighting, cameras, and sensors to achieve and maintain operational control of the border. Finally, in section 102(c) of IIRIRA, Congress granted to the Secretary of Homeland Security the authority to waive all legal requirements that I, in my sole discretion, determine necessary to ensure the expeditious construction of barriers and roads authorized by section 102 of IIRIRA.

Determination and Waiver

Section 1

The United States Border Patrol Big Bend Sector is an area of high illegal entry. Between fiscal year 2021 and fiscal year 2025, Border Patrol apprehended over 89,000 illegal aliens attempting to enter the United States between border crossings in the Big Bend Sector. In that same time period Border Patrol seized over 87,574 pounds of marijuana, over 867 pounds of cocaine, over 1,156 pounds of methamphetamine, over 12 pounds of heroin, and over 94 pounds of fentanyl.

Since the President took office, DHS has delivered the most secure border in history. More can and must be done, however. As the statistics cited above demonstrate, the Big Bend Sector is an area of high illegal entry where illegal aliens regularly attempt to enter the

United States and smuggle illicit drugs, and given my mandate to achieve and maintain operational control of the border, I must use my authority under section 102 of IIRIRA to install additional barriers and roads in the Big Bend Sector. Therefore, DHS will take immediate action to construct additional barriers and roads in a segment of the border in the Big Bend Sector. The segment where such construction will occur is referred to herein as the “project area,” which is more specifically described in Section 2 below.

Section 2

I determine that the following area in the vicinity of the United States border, located in the state of Texas within the U. S. Border Patrol Big Bend Sector is an area of high illegal entry (the “project area”): Starting at approximately GPS point 29.7275568–101.6848011 and extending east to approximately GPS point 29.727557–102.684802.

There is presently an acute and immediate need to construct additional physical barriers and roads in the vicinity of the border of the United States in order to prevent unlawful entries into the United States in the project area pursuant to section 102(a) and 102(b) of IIRIRA. In order to ensure the expeditious construction of additional physical barriers and roads in the project area, I have determined that it is necessary that I exercise the authority that is vested in me by section 102(c) of IIRIRA.

Accordingly, pursuant to section 102(c) of IIRIRA, I hereby waive in their entirety, with respect to the construction of physical barriers and roads (including, but not limited to, accessing the project areas, creating and using staging areas, the conduct of earthwork, excavation, fill, and site preparation, and installation and upkeep of physical barriers, roads, supporting elements, drainage, erosion controls, safety features, lighting, cameras, and sensors) in the project area, all of the following statutes, including all federal, state, or other laws, regulations, and legal requirements of, deriving from, or related to the subject of, the following statutes, as amended: The National Environmental Policy Act (Pub. L. 91–190, 83 Stat. 852 (42 U.S.C. 4321 *et seq.*)); the Endangered Species Act (Pub. L. 93–205, 87 Stat. 884 (16 U.S.C. 1531 *et seq.*)); the Federal Water Pollution Control Act (commonly referred to as the Clean Water Act (33 U.S.C. 1251 *et seq.*)); the National Historic Preservation Act (Pub. L. 89–665, 80 Stat. 915, as amended, repealed, or replaced by Pub.