

SUPPLEMENTARY INFORMATION: Cancer immunotherapy is a recent approach where tumor associated antigens (TAAs), which are primarily expressed in human tumor cells, and not expressed or minimally expressed in normal tissues, are employed to generate a tumor-specific immune response. Specifically, these antigens serve as targets for the host immune system and elicit responses that result in tumor destruction.

The initiation of an effective T-cell immune response to antigens requires two signals. The first one is antigen-specific via the peptide/major histocompatibility complex and the second or "costimulatory" signal is required for cytokine production, proliferation, and other aspects of T-cell activation.

The patents and patent applications describe a vaccine technology, TRICOM, in conjunction with tumor associated antigens (TAAs). The TRICOM technology employs avirulent poxviruses to present a combination of costimulatory signaling molecules with tumor-associated antigens (TAAs) to activate T-cells and break the immune systems tolerance towards cancer cells. This is achieved using recombinant poxvirus DNA vectors that encode both T-cell costimulatory molecules and TAAs. The combination of the three (3) costimulatory molecules B7.1, ICAM-1 and LFA-3, hence the name TRICOM, has been shown to have more than the additive effect of each costimulatory molecule when used individually to optimally activate both CD4+ and CD8+ T cells. When a TRICOM based vaccine expressing TAAs is administered it greatly enhances the immune response against the malignant cells expressing those TAAs. The addition of the two well-known TAAs, carcinoembryonic antigen (CEA) and MUC-1 to the TRICOM vector results in the PANVAC vaccine, which is used in a prime and boost vaccine strategy. It is well established that the over-expression of these two (2) TAAs are associated with the presence of a variety of carcinomas; including colorectal cancer and therefore PANVAC can potentially be an effective cancer vaccine for colorectal cancer. Additionally, new tumor associated antigens can also be used with TRICOM to develop novel vaccines. For example, Brachyury, well known for its role in developmental cell biology and recently been implicated in tumor cell invasion and metastasis, has been shown to be aberrantly expressed in several tumors including colorectal tumors. As a result, Brachyury is being used as a tumor associated antigen along with TRICOM and has potential as a

cancer immunotherapeutic vaccine for the treatment of several tumors including colorectal cancer.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective exclusive license may be granted unless within thirty (30) days from the date of this published notice, the NIH 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 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: May 23, 2012.

Richard U. Rodriguez,
Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

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DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Intent To Request Approval From OMB of One New Public Collection of Information: Baseline Assessment for Security Enhancement (BASE) Program for Public Transportation Systems

AGENCY: Transportation Security Administration, DHS.

ACTION: 60-day Notice.

SUMMARY: The Transportation Security Administration (TSA) invites public comment on a new Information Collection Request (ICR) abstracted below that we will submit to the Office of Management and Budget (OMB) for approval in compliance with the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. This voluntary collection allows TSA to conduct transportation security-related assessments during site visits with security and operating officials of transit agencies.

DATES: Send your comments by July 30, 2012.

ADDRESSES: Comments may be emailed to TSAPRA@dhs.gov or delivered to the

TSA PRA Officer, Office of Information Technology (OIT), TSA-11, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598-6011.

FOR FURTHER INFORMATION CONTACT: Susan Perkins at the above address, or by telephone (571) 227-3398.

SUPPLEMENTARY INFORMATION:

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation is available at www.reginfo.gov. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

Purpose of Data Collection

Approximately 6,000 transit service providers, commuter railroads, and long distance passenger railroad providers operate in the United States.¹ Mass transit and passenger rail systems provide transportation services through buses, rail transit, commuter rail, long-distance rail, and other, less common types of service (cable cars, inclined planes, funiculars, and automated guideway systems). These systems can also include "demand response services" for seniors and persons with disabilities, as well as vanpool/rideshare programs and taxi services operated under contract with a public transportation agency.

TSA is required to "assess the security of each surface transportation mode and evaluate the effectiveness and efficiency of current Federal Government surface transportation

¹ TSA, "Transportation Sector-Specific Plan Mass Transit Modal Annex", page 4 (May 2007).

security initiatives.” E.O. 13416, sec. 3(a) (Dec. 5, 2006). While many transit systems have security and emergency response plans or protocols in place, no single database exists, nor is there a consistent approach to evaluating the extent to which security programs are in place across public transportation systems.

TSA developed the Baseline Assessment for Security Enhancement (BASE) program for public transportation systems to evaluate the status of security and emergency response programs throughout the nation.² In particular, a BASE review assesses the security measures of public transportation systems and gathers data used by TSA to address its responsibilities, such as evaluating “effectiveness and efficiency of current Federal Government surface transportation security initiatives” and developing modal specific annexes to the Transportation Systems Sector Specific Plan that include “an identification of existing security guidelines and requirements and any security gaps * * *” E.O. 13416, sec. 3(c)(i). Reflecting its risk-based prioritization, TSA primarily conducts BASE reviews on the top 100 transit systems in the country, as identified by the Federal Transit Administration (FTA).³

Description of Data Collection

TSA’s Surface Transportation Security Inspectors (STSI) conduct BASE reviews during site visits with security and operating officials of transit and passenger rail systems. The STSIs capture and document relevant information using a standardized electronic checklist. Advance coordination and planning ensures the efficiency of the assessment process. As part of this, transit and passenger rail systems may also obtain a checklist in advance from TSA and conduct self-assessments of their security readiness. All BASE reviews are done on a voluntary basis.

The BASE checklist guides the collection of information and encompasses review of security plans, programs, and procedures employed by transit and passenger rail systems in implementing the recommended TSA/FTA Security and Emergency Management Action Items for Transit

Agencies (Action Items).⁴ During a review, STSIs collect information from the review of transit and passenger rail system documents, plans, and procedures; interviews with appropriate public transportation agency personnel, to gain process insight; and system observations prompted by questions raised during the document review and interview stages. TSA subject matter experts can then analyze this information. If information in completed assessments meets the requirements of 49 CFR parts 15 and 1520, which would mean that disclosure of the information would be detrimental to the security of transportation, TSA will designate and mark the data as “Sensitive Security Information,” and protect it in accordance with the requirements set forth in those regulations.

Use of Results

A BASE review evaluates a public transportation agency’s security program components using a two-phased approach: (1) Field collection of information, and (2) analysis/evaluation of collected information. The information collected by TSA through BASE reviews strengthens the security of transit and passenger rail systems by supporting security program development (including grant programs), and the analysis/evaluation provides a consistent road map for transit and passenger rail systems to address security and emergency program vulnerabilities. In addition, a public transportation system that undergoes a BASE assessment review is provided with a report of results that can be used by the system to identify and prioritize vulnerabilities to enhance security.

Specifically, the information collected will be used as follows:

1. To develop a baseline understanding of a public transportation agency’s security and emergency management processes, procedures, policies, programs, and activities against security requirements and recommended security practices published by TSA and FTA.
2. To enhance a public transportation agency’s overall security posture through collaborative review and discussion of existing security activities, identification of areas of potential weakness or vulnerability, and development of remedial recommendations and courses of action.

3. To identify programs and protocols implemented by a public transportation agency that represent an “effective” or “smart” security practice warranting sharing with the transit and passenger rail community as a whole to foster general enhancement of security in the mass transit and passenger rail mode.

4. To inform TSA’s development of security strategies, priorities, and programs for the most effective application of available resources, including funds distributed under the Transit Security Grant Program, to enhance security in the Nation’s transit and passenger rail systems.

While TSA has not set a limit on the number of public transportation system BASE program reviews to conduct, TSA estimates it will conduct approximately 100 public transportation system BASE reviews on an annual basis and does not intend to conduct more than one BASE review per transit or passenger rail system in a single year. The total hour burden dedicated to the assessment and collection of security-related documents for review varies depending upon the size of the system and scope of its security program and activities. The hours estimated represent a sampling of BASE reviews completed in 2010. The sampling was derived from 15 public transportation agencies varying in size from small to large. Actual inspection hours were utilized in the sampling. TSA estimates that the hour burden per public transportation agency to engage its security and/or operating officials with inspectors in the interactive BASE program review process is approximately 18 hours for a small public transportation agency, approximately 144 hours for a large public transportation agency, and approximately 46 hours for a moderately-sized agency. Thus, the total annual hour burden for the BASE program review (140 agencies identified) is estimated on the low end of 2520 hours ($140 \times 18 = 2520$) annually and the high end of 6440 hours ($140 \times 46 = 6440$) annually. This number will most likely increase as additional public transportation agencies volunteer to participate.

Issued in Arlington, Virginia, on May 23, 2012.

Susan Perkins,

TSA Paperwork Reduction Act Officer, Office of Information Technology.

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² A separate program within TSA also conducts BASE reviews to assess security measures related to highway transportation, notice of which will be published separately in the **Federal Register**.

³ A current list of the top 100 transit systems can be viewed on the National Transit Database Web site at <http://www.ntdprogram.gov/ntdprogram/>.

⁴ Action Items are available for download at http://www.tsa.gov/assets/pdf/mass_transit_action_items.pdf.