

achieve \$10 billion in scorable Medicaid savings over 5 years while at the same time make progress toward meaningful longer-term program changes to better serve beneficiaries. The Commission may discuss the need to divide into sub-groups for the purpose of focusing on particular issues within this broad subject, including a discussion of which members would serve on which sub-group.

**Procedure and Agenda:** This meeting is open to the public. There will be a public comment period at the meeting. The Commission may limit the number and duration of oral presentations to the time available. We will request that you declare at the meeting whether or not you have any financial involvement related to any services being discussed.

After the public and CMS presentations, the Commission will deliberate openly on the topic. Interested persons may observe the deliberations, but the Commission will not hear further comments during this time except at the request of the Chairperson. The Commission will also allow an open public session for any attendee to address issues specific to the topic.

**Authority:** 5 U.S.C. App. 2, section 10(a)(1) and (a)(2).

Dated: August 2, 2005.

**Mark B. McClellan,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 05-15522 Filed 8-2-05; 1:08 pm]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Proposed Collection: Comment-Request; Revision of OMB No. 0925-0002/exp. 08/31/05, Individual Ruth L. Kirschstein National Research Service Award Applications and Related forms**

**SUMMARY:** In compliance with the requirement of Section 3407(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Director (OD), Office of Extramural Research (OER), the National Institutes of Health (NIH) has submitted to the Office of management and budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March 16, 2005, Volume 70, No. 50, page 12889 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days

for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

#### **Proposed Collection**

**Title:** Individual Ruth L. Kirschstein National Research Service Award Applications and Related Forms.

**Type of Information Collection Request:** Revision, OMB 0925-0002, Expiration Date 8/31/05.

**Form Numbers:** PHS 416-1, 416-9, 416-5, 416-7, 6031, 6031-1.

**Need and Use of Information Collection:** The 416-1 and 416-9 are used by individuals to apply for direct research training support. Awards are made to individual applicants for specified training proposals in biomedical and behavioral research, selected as a result of a national competition. The other related forms (PHS 416-5, 416-7, 6031, 6031-1) are used by these individuals to activate, terminate, and provide for payback of a National Research Service Award.

**Frequency of response:** Applicants may submit applications for published receipt dates. If awarded, annual progress is reported and trainees may be appointed or reappointed.

**Affected public:** Individuals or Households; Business or other for-profit; Not-for-profit institutions; Federal Government; and State, local or tribal government.

**Type of Respondents:** Adult scientific trainees and professionals.

The annual reporting burden is as follows:

**Estimated Number of Respondents:** 51,822;

**Estimated Number of Responses per respondent:** 1;

**Average Burden Hours Per Response:** 2.7; and

**Estimated total Annual Burden Hours Requested:** 124,034.

**Request for comments:** Written comments and/or suggestions from the public and affected agencies are invited on 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 minimize 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.

**Direct Comments to OMB:** Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time should be directed to the Office of Management and Budget, Office of Regulatory Affairs, New executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Marcia Hahn, Division of Grants Policy, Office of Policy for Extramural Research Administration, NIH, Rockledge 1 Building, Room 3515, 6705 Rockledge Drive, Bethesda, MD 20892-7974, or call non-toll-free number (301) 435-0932, or E-mail your request, including your address to: [hahnm@od.nih.gov].

**Comments Due Date:** Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: July 27, 2005.

**Dr. Charles Mackay,**

*Chief, Project Clearance Branch, OPERA, OER, National Institutes of Health.*

[FR Doc. 05-15441 Filed 8-3-05; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Government-Owned Inventions; Availability for Licensing**

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**ADDRESSES:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing

to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

#### **Immunogenic Peptides From Human Papillomavirus Type 16 E2**

Samir N. Khleif and Jiahua Qian (NCI). U.S. Provisional Application No. 60/671,463 filed 15 Apr. 2005 (DHHS Reference No. E-155-2005/0-US-01). U.S. Provisional Application No. 60/680,000 filed 12 May 2005 (DHHS Reference No. E-155-2005/1-US-01). *Licensing Contact:* Michael Shmilovich; 301/435-5019; [shmilovm@mail.nih.gov](mailto:shmilovm@mail.nih.gov).

Available for licensing, commercial development and biological materials licensing are CD8+ T cell epitopes from HPV16 E2 (Human Papillomavirus serotype 16 E2). These epitopes generated from amino acid positions 69-77 (ALQAIQL) and 138-147 (YICEEASVTV) bind to HLA.A2 and elicit CD8+ cytotoxic T cell responses that lyse tumor cells of low-grade cervical neoplasia (wart).

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

#### **HIV gp41-Membrane Proximal Region Arrayed on Hepatitis B Surface Antigen Particles for HIV Diagnostic and Vaccine Applications**

Richard T. Wyatt (NIAID), Sanjay K. Phogat (NIAID), Ira Berkower (FDA). U.S. Provisional Application No. 60/653,930 filed 18 Feb. 2005 (DHHS Reference No. E-123-2005/0-US-01). *Licensing Contact:* Susan Ano; 301/435-5515; [anos@mail.nih.gov](mailto:anos@mail.nih.gov).

This technology describes vectors encoding the membrane proximal region (MPR) and select variants from HIV-1 gp41 linked to the hepatitis B surface antigen (HBsAg) and the resulting expressed particles for use in HIV diagnostic and vaccine applications. HIV-1 gp41 membrane proximal region contains two epitopes recognized by broadly neutralizing human monoclonal antibodies 2F5 and 4E10. However, immunization with gp41 MPR or the 2F5 or 4E10 epitopes have failed to raise neutralizing antibodies. In the subject technology, the particles were shown to bind antibodies from broadly neutralizing human sera and to the two known broadly neutralizing antibodies

2F5 and 4E10 with high relative affinities, demonstrating that the relevant epitopes are accessible for antibody binding and the potential utility of the particles in diagnostic applications. Additionally, these particles could be used to screen phage-display libraries for novel broadly cross-reactive neutralizing antibodies, of which only five are currently known. These particles could also be used for selection of MPR specific B cells. Lastly, these particles have been shown to be immunogenic and raise antibodies that recognize HIV-1 Env gp160 expressed on the cell surface. These immunogens can elicit neutralizing antibodies specific for HIV gp41 MPR, the MPR of gp41 is highly conserved across various HIV clades and therefore is likely to generate broadly neutralizing antibodies when administered in a proper presentation in a lipid context as is the case in HBsAg particles. Multiple copies of the MPR of HIV-1 gp41 arrayed on the particles could significantly increase the immunogenic potential compared to monomeric molecules. An increase of this nature has been observed with HBsAg and HPV virus-like particles in hepatitis B and cervical cancer vaccines, respectively, suggesting that particulate array may improve the presentation of selected epitopes to the immune system.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

#### **North-2'-Deoxy-Methanocarbothymidines as Antiviral Agents Against Poxviruses**

Christopher K. Tseng (NIAID), Victor E. Marquez (NCI). U.S. Provisional Application No. 60/684,811 filed 25 May 2005 (DHHS Reference No. E-047-2005/0-US-01). *Licensing Contact:* Robert M. Joynes; 301/594-6565; [joynesr@mail.nih.gov](mailto:joynesr@mail.nih.gov).

This invention relates to a method for the prevention or treatment of poxvirus infection by administering an effective amount of an antiviral agent comprising a carbocyclic 2'-deoxynucleoside analog (as described in U.S. Patent Nos. 5,629,454 and 5,869,666) to an individual in need thereof. North-methanocarbothymidine (N-MCT), a thymidine analog with a pseudosugar moiety locked in the northern conformation, which was previously shown to exert strong activity against herpes simplex virus types 1 and 2, has been identified as exhibiting potent activity against poxviruses. N-MCT effectively blocks poxvirus synthesis through its phosphorylated metabolite, which is more efficiently produced in

poxvirus-infected cells. This compound is approximately seven times more potent than cidofovir against vaccinia and cowpox in cell culture. The higher potency and target specificity of N-MCT against poxvirus, as well as its high margin of safety, makes it a highly desirable agent against the poxviridae family. In addition, the mechanism of N-MCT may be different from that of cidofovir, making it even more desirable due to the scarcity of the potential available efficacious anti-pox agents currently under development. This method of treating poxvirus with the described analogs is now available for licensing.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

#### **A Novel Interleukin-12 (IL-12) Inducing Protein Isolated from *Toxoplasma gondii* Inflammatory Profilin (TGIP)**

Alan Sher and Felix Yarovinsky (NIAID). U.S. Provisional Application 60/641,429 filed 06 Jan 2005 (DHHS Reference No. E-046-2005/0-US-01). *Licensing Contact:* Michael Shmilovich; 301/435-5019; [shmilovm@mail.nih.gov](mailto:shmilovm@mail.nih.gov).

Available for licensing and commercial development is a patent pending technology for identifying and isolating a novel interleukin-12 (IL-12) inducing protein isolated from *Toxoplasma gondii* (*T. gondii*), and to methods of using this protein for modulating immune responses. Interferon- $\gamma$  (IFN- $\gamma$ ) is critical in host resistance to many pathogens and also has potent anti-tumor effects on certain IFN- $\gamma$  sensitive tumors. IL-12 triggers the synthesis of IFN- $\gamma$ , thus compounds that stimulate IL-12 production are likely to contribute to stimulation of host resistance to pathogens and IFN- $\gamma$  sensitive tumors.

The isolated protein, *Toxoplasma gondii* Inflammatory Profilin (TGIP), also known as PFTG (Profilin *Toxoplasma gondii*) binds to Toll-like receptor 11 (TLR 11) and induces dendritic cell IL-12 production. The patent as filed discloses isolated TGIP polypeptide sequences, fusion proteins comprising a TGIP and antigen polypeptide portions, isolated nucleic acids encoding a fusion protein, and a promoter-linked polynucleotide encoding TGIP. Also described are methods for inducing a IL-12 response, a method for administering isolated TGIP for the treatment of pathogenic infection, a method for treating an IFN-

$\gamma$  sensitive cancer in a subject and methods for enhancing immune response against an antigen in a subject. Also with the scope of the invention are anti-TGIP antibodies. Since IL-12 also has other immunostimulatory effects, further identification of IL-12 inducing compounds will be useful for the design of immunostimulatory and adjuvant agents.

This research is described in Yarovsky *et al.*, "LR11 activation of dendritic cells by a protozoan profilin-like protein," *Science* 2005 Jun 10; 308(5728):1626-9. Epub 2005 Apr 28.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

#### Ultrahigh-Resolution Fiber-Optic Confocal Microscope And Method

Ilko Ilev (FDA/CDRH), Ronald Waynant (FDA/CDER), Israel Gannot (NICHD), Amir Gandjbakhche (NICHD).

U.S. Provisional Application No. 60/671,104 filed 14 Apr. 2005 (DHHS Reference No. E-038-2005/0-US-01).

Licensing Contact: Michael Shmilovich; 301/435-5019;

[shmilovm@mail.nih.gov](mailto:shmilovm@mail.nih.gov).

Public Health Service investigators have invented a single-mode fiber-optic

confocal microscope for which a licensee and commercial developer is sought. The ultrahigh-resolution fiber-optic confocal microscope has an illumination system; three single-mode optical fibers, each optically coupled to a fiber coupler; a sample support stage arranged to receive illumination radiation from an end of one of the single-mode optical fibers; a detector arranged to receive output radiation from one of the single-mode optical fibers; and a lock-in amplifier electrically connected to the detector and the illumination system. The illumination system is adapted to provide illumination radiation that has a time-varying strength correlated with the detector by the lock-in amplifier. The invention provides improved methods and designs for confocal microscopy.

#### Integrin Alpha-V Beta-3 Antagonists for Use in Imaging and Therapy

S. Narasimhan Danthi *et al.* (CC). U.S. Patent Application No. 10/911,988 filed 04 Aug 2004 (DHHS Reference No. E-170-2004/0-US-01).

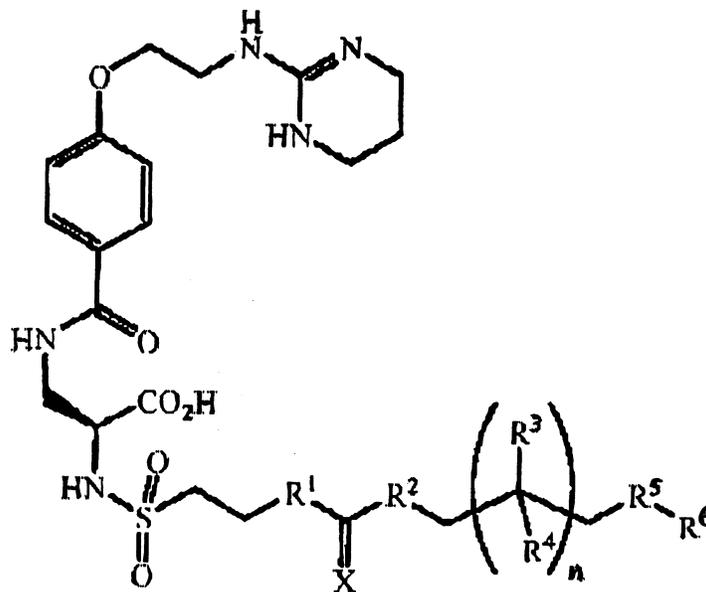
Licensing Contact: Michael Shmilovich; 301/435-5019;

[shmilovm@mail.nih.gov](mailto:shmilovm@mail.nih.gov).

Available for licensing are compounds as shown below for imaging

and therapy. These compounds are integrin  $\alpha_v\beta_3$  receptor antagonists and are described and claimed in a patent application available for review. The patent application also includes claim coverage for the administration of these compounds containing a detectable moiety or pharmaceutical compositions of such imaging agents as part of the imaging of cells that express integrin  $\alpha_v\beta_3$ .

in which: X is either NH, O, or S; n is zero or a positive integer; R<sub>1</sub> is either CH<sub>2</sub>, NH, O, or S; R<sub>2</sub> is either CHR<sub>7</sub>, NR<sub>7</sub>, O, or S, in which R<sub>7</sub> is H or alkyl; R<sub>3</sub> and R<sub>4</sub>, which are either the same or different from each other, are either H, alkyl, aryl, arylalkyl, cycloalkyl, cycloalkylalkyl, alkyl-substituted aryl, (alkylsubstitutedaryl)alkyl, hydroxy-substituted alkyl, hydroxy-substituted aryl, or (hydroxy-substituted aryl)alkyl; R<sub>5</sub> is either CH<sub>2</sub>, NH, O, or S; and R<sub>6</sub> is either H or C(=Y)-R<sub>8</sub>-R<sub>9</sub>, in which: Y is either NH, O, or S; R<sub>8</sub> is either CHR<sub>10</sub>, NR<sub>10</sub>, O, or S, in which R<sub>10</sub> is H or alkyl; and R<sub>9</sub> is either H, alkyl, aryl, arylalkyl, cycloalkyl, cycloalkylalkyl, alkylsubstituted aryl, (alkyl-substituted aryl)alkyl, hydroxy-substituted alkyl, hydroxy-substituted aryl, or (hydroxy-substituted aryl)alkyl.



Dated: July 19, 2005.

**Steven M. Ferguson,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

[FR Doc. 05-15346 Filed 8-3-05; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF HOMELAND SECURITY

[DHS 2005-0011]

RIN 1650-AA01

### United States Visitor and Immigrant Status Indicator Technology Program; Notice on Automatic Identification of Certain Nonimmigrants Exiting the United States at Select Land Border Ports-of-Entry

**AGENCY:** Border and Transportation Security Directorate, Department of Homeland Security.

**ACTION:** Notice with request for comments.

**SUMMARY:** The Department of Homeland Security has established the United States Visitor and Immigrant Status Indicator Technology Program, an integrated, automated entry-exit system that records the arrival and departure of aliens; verifies aliens' identities; and authenticates aliens' travel documents through comparison of biometric identifiers. On August 31, 2004, the Department of Homeland Security implemented the second phase of the United States Visitor and Immigrant Status Indicator Technology Program by publishing an interim rule in the **Federal Register** authorizing collection of biometric data from travelers upon admission at the 50 most highly trafficked land border ports-of-entry. This Notice informs the public of the further expansion of the second phase of the program by establishing a limited testing or proof of concept protocol for automatically documenting the exits and any subsequent re-entries of nonimmigrant travelers at five United States land border ports-of-entry crossings utilizing radio frequency identification (RFID) technology. The purpose of this testing is to determine if RFID technology can improve the efficiency of processing individuals who seek to enter or exit the United States at a land border port-of-entry. This program of testing will last approximately one year.

**DATES: Effective Dates:** This Notice is effective August 4, 2005. Written comments must be submitted on or before October 3, 2005.

**ADDRESSES:** You may submit comments identified by DHS-2005-0011 to the Docket Management Facility at the EPA. To avoid duplication, please use only one of the following methods:

- Web site: <http://www.epa.gov/edocket>. Follow the instructions for submitting comments at that Web site.
- Mail: Written comments may be submitted to Craig Howie, US-VISIT, Border and Transportation Security; Department of Homeland Security; 1616 North Fort Myer Drive, 18th Floor, Arlington, VA 22209.

Submitted comments may be inspected at 1616 North Ft. Myer Drive, Arlington, VA 22209 between 9 a.m. and 5 p.m., Monday through Friday except Federal holidays. Arrangements to inspect submitted comments should be made in advance by calling (202) 298-5200. You may also find this docket on the Internet at <http://www.epa.gov/edocket>.

**FOR FURTHER INFORMATION, CONTACT:** Craig Howie, Senior Regulatory Analyst, US-VISIT, Border and Transportation Security, Department of Homeland Security, 1616 Fort Myer Drive, 18th Floor, Arlington, Virginia 22209, (202) 298-5200.

**Authority:** 8 U.S.C. 1103, 1184, 1185, 1258, 1281, 1282, 1301-1306, E.O. 13323.

#### SUPPLEMENTARY INFORMATION:

##### I. Statutory Authority for US-VISIT

The Department of Homeland Security (DHS) established the United States Visitor and Immigrant Status Indicator Technology Program (US-VISIT) in accordance with several statutory mandates that collectively require DHS to create an integrated, automated entry and exit system (entry-exit system) that records the arrival and departure of aliens; verifies the identities of aliens at a land border port-of-entry; and authenticates travel documents presented by such aliens through the comparison of biometric identifiers at a land border port-of-entry. Aliens subject to US-VISIT may be required to provide finger scans, photographs, or other biometric identifiers upon arrival in, or departure from, the United States. DHS views US-VISIT as a biometric driven program designed to enhance the security of United States citizens, permanent residents, and visitors while expediting legitimate travel and trade, ensure the integrity of the immigration system, and protect visitors' personal information.

The statutes that authorize DHS to establish US-VISIT include, but are not limited to:

- Section 2(a) of the Immigration and Naturalization Service Data

Management Improvement Act of 2000, Public Law 106-215, 114 Stat. 337 (June 15, 2000);

- Section 205 of the Visa Waiver Permanent Program Act of 2000, Public Law 106-396, 114 Stat. 1637, 1641 (Oct. 30, 2000);

- Section 414 of the Uniting and Strengthening America by Providing Appropriate Tools Required To Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), Public Law 107-56, 115 Stat. 271, 353 (Oct. 26, 2001); and

- Section 302 of the Enhanced Border Security and Visa Entry Reform Act of 2002 (Border Security Act) Public Law 107-173, 116 Stat. 543, 552 (May 14, 2002).

DHS provided detailed abstracts of the particular sections of the statutes that established and authorized the US-VISIT program in two prior rulemakings. See 69 FR 468 (Jan. 5, 2004); 69 FR 53318 (Aug. 31, 2004).

In addition, on December 17, 2004, the Intelligence Reform and Terrorism Prevention Act of 2004 (IRPTA), Public Law 108-458, sec. 7208, 118 Stat. 3638, 3817 (Dec. 17, 2004), specifically addressed biometric entry and exit, and subsection (c) calls for the Secretary to accelerate the full implementation of the US-VISIT program. The proof of concept protocol described within this Notice assists DHS in accelerating the full implementation of US-VISIT.

##### II. Implementation of US-VISIT, Phases One and Two

On January 5, 2004, DHS published an interim rule in the **Federal Register** establishing US-VISIT at air and sea ports-of-entry designated by notice in the **Federal Register**. See 69 FR 468. Also on January 5, 2004, DHS published a notice in the **Federal Register**, 69 FR 482, designating 115 airports and 14 seaports for the collection of biometric data from certain nonimmigrant travelers upon arrival to the United States under the US-VISIT program. Since January 5, 2004, travelers applying for admission pursuant to a nonimmigrant visa at designated air and seaports have been required to submit finger scans and photographs.

The January 5, 2004, interim rule also provided for the Secretary to establish pilot programs at up to fifteen air or sea ports of entry, to be identified by notice in the **Federal Register**, through which DHS may require certain nonimmigrant travelers who depart from a designated air or sea port-of-entry to provide specified biometric identifiers and other evidence at the time of departure. See 8 CFR 215.8. On January 5, 2004, DHS published a notice in the **Federal**