TABLE A—ANNUALIZED BURDEN ESTIMATES FOR CHIS 2009—Continued

| Type of respondent | Form type | Number of respondents | Frequency of response | Average time per response (hours) | Annual hour burden |
|---|---|---|---|---|---|
| Adolescents | Adolescent Pilot | 8 | 1 | 2/60 | .27 |
| | Adolescent Survey | 2,000.00 | 1 | 2/60 | 66.67 |
| Total | | 26,083 | | | 3,276.94 |

*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 proposed 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.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Nancy Breen, Ph.D., Project Officer, National Cancer Institute, EPN 4005, 6130 Executive Boulevard MSC 7344, Bethesda, Maryland 20852–7344, or call non-toll free number 301–496–8500 or email your request, including your address to: *breenn@mail.nih.gov.*

*Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 60 days of this publication.

Dated: August 13, 2008.

**Vivian Horovitch-Kelley,**

*NCI Project Clearance Liaison Office, National Institutes of Health.*

[FR Doc. E8–19453 Filed 8–21–08; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Licensing and/or Cooperative Research and Development Agreement (CRADA) Opportunities—Enhanced T-cell Activation by Costimulation: A Potentially Novel Approach for the Prevention and/or Therapy of Cancer (Excluding Prostate Diseases and Melanoma) and for Infectious Diseases

**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. Cooperative Research and Development Agreement (CRADA) opportunities are also available.

**FOR FURTHER INFORMATION CONTACT:** Licensing information and copies of the U.S. patent applications listed below may be obtained by contacting Mojdeh Bahar, J.D., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville MD 20852; *telephone:* 301/435–2950; *e-mail: baharm@mail.nih.gov*. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications. If interested in a Cooperative Research and Development Agreement (CRADA) Opportunity, please submit a statement of interest and capability to Kevin Brand, J.D., in the NCI Technology Transfer Center, 6120 Executive Boulevard, Suite 450, Rockville MD 20852; *telephone:* 301/451–4566; *e-mail: kb229t@nih.gov*.

**SUPPLEMENTARY INFORMATION:**

**Description of Technology**

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 results 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 present technology describes recombinant poxvirus vectors encoding at least three or more costimulatory molecules and tumor associated antigens (TAAs). The use of three costimulatory molecules such as B7.1, ICAM–1 and LFA–3 (TRICOM®) has been shown to act in synergy with several tumor antigens and antigen epitopes to activate T cells. The effects with TRICOM® were significantly greater than with one or two costimulatory molecules. Laboratory results support the greater effect of TRICOM® to activate both $CD4^+$ and $CD8^+$ T cells. The invention also describes the use of at least one target antigen or immunological epitope as an immunogen or vaccine in conjunction with TRICOM®. The antigens include but are not limited to carcinoembryonic antigen (CEA) and MUC–1. The combination of CEA, MUC–1, and TRICOM® is referred to as PANVAC®.

**Availability**

The technology is available for exclusive and non-exclusive license in combinations and fields of use. Some potential licensing opportunities involving recombinant poxviral vectors containing transgenes are as follows:

(1) TRICOM® (alone or with a transgene for a tumor antigen and/or an immunostimulatory molecule);

(2) The antigens only, including but not limited to CEA and MUC–1;
PANVAC®; and
(3) Recombinant fowlpox–GM–CSF.

**Applications and Modality**

Vector-based TRICOM® (alone or with a transgene(s) for a tumor antigen and/or an immunostimulatory molecule(s)), PANVAC® and combinations thereof can be a potential novel approach for the prevention or treatment of cancer (with the exclusion of prostate cancer, prostatic diseases, and melanoma) and infectious diseases.

**Advantages**

- The technology is beyond proof-of-concept, supported by laboratory results and publications.
- Phase I and Phase II clinical data available (to qualified licensees).
- Fewer validation studies are required compared to other immunotherapy related technologies.

**Development Status**

Phase I and Phase II results available (to qualified licensees) for poxvirus recombinants containing transgenes for TRICOM®, CEA–TRICOM®, and PANVAC®. Further clinical studies are ongoing.

**Inventors**

Jeffrey Schlom (NCI) *et al.* (Inventor Web page: *http://ccr.cancer.gov/Staff/staff.asp?profileid=5444*).

**Publications**

1. Kudo-Saito C, Wansley EK, Gruys ME, Wiltrout R, Schlom J and Hodge JW. Combination therapy of an orthotopic renal cell carcinoma model employing intratumoral vector-mediated costimulation and systemic IL–2. *Clin Cancer Res.* 13:1936–1946, 2007.

2. Chakraborty M, Schlom J, and Hodge JW. The combined activation of positive costimulatory signals with modulation of a negative costimulatory signal for the enhancement of vaccine mediated T-cell responses. *Cancer Immunol Immunother.* 56:1471–1484, 2007.

3. Kudo-Saito C, Garnett CT, Wansley EK, Schlom J, and Hodge JW. Intratumoral delivery of vector mediated IL–2 in combination with vaccine results in enhanced T-cell avidity and anti-tumor activity. *Cancer Immunol Immunother.* 56:1897–1910, 2007.

4. Garnett CT, Schlom J, and Hodge JW. Combination of docetaxel and recombinant vaccine enhances T-cell responses and antitumor activity: Effects of docetaxel on immune enhancement. *Clin Cancer Res.* (in press).

5. Chakraborty M, Gelbard A, Carrasquillo JA, Yu S, Mamede M, Park CH, Camphuasen K, Schlom J, and Hodge JW. Use of radiolabeled monoclonal antibody to enhance vaccine-mediated antitumor effects. *Cancer Immunol Immunother.* 56:1471–1484, 2007.

6. Litzinger MT, Fernando R, Curiel TJ, Grosenbach DW, Schlom J, and Palena C. The IL–2 immunotoxin denileukin diftitox reduces regulatory T-cells and enhances vaccine-mediated T-cell immunity. *Blood* 110:3192–3201, 2007.

7. Gelbard A, Garnett CT, Abrams SI, Patel V, Gutkind JS, Palena C, Tsang KY, Schlom J, and Hodge JW. Combination chemotherapy and radiation of human squamous cell carcinoma of the head and neck augments CTL-mediated lysis. *Clin Cancer Res.* 12:1897–1905, 2006.

8. Kaufman HL, Cohen S, Cheung K, DeRaffele, Mitcham J, Moroziewicz D, Schlom J, and Hesdorffer C. Local delivery of vaccinia virus expressing multiple costimulatory molecules for the treatment of established tumors. *Human Gene Ther.* 17:239–244, 2006.

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10. Palena C, Foon KA, Panicali D, Yafal AG, Chinsangaram J, Hodge JW, Schlom J, and Tsang KY. A potential approach to immunotherapy of chronic lymphocytic leukemia (CLL): enhanced immunogenicity of CLL cells via infection with vectors encoding for multiple costimulatory molecules. *Blood* 106:3515–3523, 2005.

11. Yang S, Hodge JW, Grosenbach DW, and Schlom J. Vaccines with enhanced costimulation maintain high avidity memory CTL. *J. Immunol.* 175:3715–3723, 2005.

12. Yang S, Tsang KY, and Schlom J. Induction of higher avidity human CTL by vector-mediated enhanced costimulation of antigen-presenting cells. *Clin Cancer Res.* 11:5603–5615, 2005.

13. Hodge JW, Chakraborty M, Kudo-Saito C, Garnett CT, Schlom J. Multiple costimulatory modalities enhance CTL avidity. *J Immunol* 174:5994–6004, 2005.

14. Tsang K-Y, Palena C, Yokokawa J, Arlen PM, Gulley JL, Mazzara GP, Gritz L, Gómez Yafal A, Ogueta S, Greenhalgh P, Manson K, Panicali D, and Schlom J. Analyses of recombinant vaccinia and fowlpox vaccine vectors expressing transgenes for two human tumor antigens and three human costimulatory molecules. *Clin Cancer Res.* 11:1597–1607, 2005.

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20. Hodge JW, Grosenbach DW, Aarts WM, Poole DJ, and Schlom J. Vaccine therapy of established tumors in the absence of autoimmunity. *Clin Cancer Res.* 9:1837–1849, 2003.

21. Aarts WM, Schlom J, and Hodge JW. Vector-based vaccine/cytokine combination therapy to enhance induction of immune responses to a self-antigen and anti-tumor activity. *Cancer Res.* 62:5770–5777, 2002.

22. Hodge JW, Sabzevari H, Yafal AG, Gritz L, Lorenz MG, Schlom J. A triad of costimulatory molecules synergize to amplify T-cell activation. *Cancer Res.* 59: 5800–5807, 1999.

**Patent Status**

1. U.S. Patent No. 6,969,609 issued November 29, 2005 as well as issued and pending foreign counterparts [HHS Ref. No. E–256–1998/0];

2. U.S. Patent Application No. 11/321,868 filed December 30, 2005 [HHS Ref. No. E–256–1998/1]; and

3. U.S. Patent No. 6,756,038 issued June 29, 2004 as well as issued and

pending foreign counterparts [HHS Ref. No. E–099–1996/0];

4. U.S. Patent No. 6,001,349 issued December 14, 1999 as well as issued and pending foreign counterparts [HHS Ref. No E–200–1990/3–US–01];

5. U.S. Patent No.6,165,460 issued December 26, 2000; as well as issued and pending foreign counterparts [HHS Ref. No E–200–1990/4–US–01];

6. U.S. Patent No. 7,118,738 issued October 10, 2006 as well as issued and pending foreign counterparts [HHS Ref. No E–154–1998/0–US–07];

7. PCT Application No. PCT/US97/12203 filed July 15, 1997 [HHS Ref. No E–259–1994/3–PCT–02];

8. U.S. Patent Application Nos. 10/197,127. and 08/686,280 filed July 17, 2002 and July 25, 1996 [HHS Ref. No E–259–1994/3–US–08 and /4–US–01];

9. U.S. Patent No. 6,946,133 issued September 20, 2005 as well as issued and pending foreign counterparts [HHS Ref. No E–062–1996/0–US–01];

10. U.S. Patent Application No. 11/606,929 filed December 1, 2006 [E–062–1996/0–US–11];

11. U.S. Patent Nos. 6,893,869, 6,548,068 and 6,045,802 issued May 17, 2005, April 15, 2003 and April 4, 2000 respectively, as well as issued and pending foreign counterparts [HHS Ref. Nos. E–260–1994/1–US–03, US–02, US–01]; and

12. U.S. Patent. Application No. 11/090,686 filed March 8, 2005 [HHS Ref. No E–260–1994/1–US–04].

**Cooperative Research and Development Agreement (CRADA) Opportunities**

A CRADA partner for the further co-development of this technology is currently being sought by the Laboratory of Tumor Immunology and Biology, Center for Cancer Research, NCI. The CRADA partner will (a) generate and characterize recombinant poxviruses expressing specific tumor-associated antigens, cytokines, and/or T-cell costimulatory factors, (b) analyze the recombinant poxviruses containing these genes with respect to appropriate expression of the encoded gene product(s), (c) supply adequate amounts of recombinant virus stocks for preclinical testing, (d) manufacture and test selected recombinant viruses for use in human clinical trials (with the exception of trials for prostatic diseases and melanoma), (e) submit Drug Master Files detailing the development, manufacture, and testing of live recombinant vaccines to support the NCI-sponsored IND and/or company-sponsored IND, (f) supply adequate amounts of clinical grade recombinant poxvirus vaccines for clinical trials conducted at the NCI Center for Cancer Research (CCR), and (g) provide adequate amounts of vaccines for extramural clinical trials, if agreed upon by the parties, and conduct clinical trials under company-sponsored or NCI-sponsored INDs. NCI will (a) provide genes of tumor-associated antigens, cytokines and other immunostimulatory molecules for incorporation into poxvirus vectors, (b) evaluate recombinant vectors in preclinical models alone and in combination therapies, and (c) conduct clinical trials (with the exception of trials for prostatic diseases and melanoma) of recombinant vaccines alone and in combination therapies.

Dated: August 14, 2008

**Richard U. Rodriguez,**

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

[FR Doc. E8–19462 Filed 8–21–08; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Neurological Disorders and Stroke; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Neurological Disorders and Stroke Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Advisory Neurological Disorders and Stroke Council; Clinical Trials Subcommittee.

*Date:* September 18, 2008.

*Closed:* 8 a.m. to 9 a.m.

*Agenda:* To review and evaluate grant applications and/or proposals.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, C Wing, Conference Room 10, Bethesda, MD 20892.

*Open:* 9 a.m. to 10 a.m.

*Agenda:* To discuss clinical trials policy.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, C Wing, Conference Room 10, Bethesda, MD 20892.

*Contact Person:* Deborah G Hirtz, MD, Acting Director, Clinical Trials Cluster, National Institute of Neurological, Disorders and Stroke, National Institute of Health, 6001 Executive Blvd., Suite 2212, Bethesda, MD 20892, (301) 496–5821, *hirtz@ninds.nih.gov*.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *www.ninds.nih.gov*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to NeurologicalDisorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: August 15, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E8–19442 Filed 8–21–08; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Neurological Disorders and Stroke; Notice of Meetings

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of meetings of the National Advisory Neurological Disorders and Stroke Council.

The meetings will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* National Advisory Neurological Disorders and Stroke Council, Training, Career Development, and Special Programs Subcommittees.

*Date:* September 17, 2008.

*Time:* 8 p.m. to 10 p.m.