Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Blood donors at Baseline Visit	3,750	1	0.12	450
Blood donors at Follow-up Visit	1720	1	0.1	172
Total				622

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address 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 the assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information 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 Dr. George Nemo, Project Officer, NHLBI, Two Rockledge Center, Room 10142, 6701 Rockledge Drive, MSC 7950, Bethesda, MD 20892–7950, or call 301–435–0075, or e-mail your request to *nemog@nih.gov.*

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

Dated: August 21, 2006.

Meg Scofield,

NHLBI Project Clearance Liaison Officer, National Institutes of Health.

[FR Doc. E6–14191 Filed 8–25–06; 8:45 am]

BILLING CODE 4140–01–P

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.

Diagnostic and Therapeutic Strategies for Metastatic Hepatocellular Carcinoma by Targeting Osteopontin

Description of Technology: Cancer is one of the leading causes of death in United States and it is estimated that there will be more than half a million deaths caused by cancer in 2006. For the last decade breast and prostate cancer survival rate has significantly decreased thanks to contribution of screening, early detection and novel therapeutics. This success needs to be translated to other cancers as well, where there is a need of novel diagnostic and therapeutic strategies for successful disease management.

Osteopontin (OPN) is a well known serum prognostic marker for breast cancer. This technology identifies a 10kD residue of OPN as a potential prognostic marker and therapeutic target for metastatic hepatocellular carcinoma (HCC). Mechanistically, OPN has been shown to be a novel substrate for MMP–9 and the 10kD fragment is demonstrated to be a mediator of cell invasion and metastasis. Short synthetic peptides against OPN have been shown to block OPN mediated cell invasion, providing a novel therapeutic approach targeting OPN. Finally, polyclonal antibodies against the 10kD fragment of OPN have been developed that can be used for detection of OPN in physiological fluids of HCC patients. This technology provides a novel therapeutic and diagnostic strategy for the management of HCC patients using OPN.

Development Status: The technology is in the pre-clinical stage, animal studies are under way.

Inventors: Vivian A. Takafuji (NCI) *et al.*

Relevant Publications:

1. A manuscript relating to this invention has been submitted for publication and will be available once accepted.

2. J Kim, SS Ki, SD Lee, CJ Han, YC Kim, SH Park, SY Cho, YJ Hong, HY Park, M Lee, HH Jung, KH Lee, SH Jeong. Elevated plasma osteopontin levels in patients with hepatocellular carcinoma. Am J Gastroenterol. 2006 Jul 18; Epub ahead of print, doi: 10.1111/j.1572–0241.2006.00679.

3. QH Ye, LX Qin, M Forgues, P He, JW Kim, AC Peng, R Simon, Y Li, AI Robles, Y Chen, ZC Ma, ZQ Wu, SL Ye, YK Liu, ZY Tang, XW Wang. Predicting hepatitis B virus-positive metastatic hepatocellular carcinomas using gene expression profiling and supervised machine learning. Nat Med. 2003 Apr; 9(4):416–423.

Patent Status: U.S. Provisional Application No. 60/805,298 filed 20 Jun 2006 (HHS Reference No. E–201–2006/0–US–01).

Licensing Status: This technology is available for licensing under an exclusive or non-exclusive patent license.

Licensing Contact: Michelle Booden, Ph.D.; 301/451–7337; *boodenm@mail.nih.gov*.

Collaborative Research Opportunity: The NCI Laboratory of Human Carcinogenesis is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize diagnostic and therapeutic strategies for metastatic hepatocellular carcinoma. Please contact Betty Tong at 301–594–4263 or *tongb@mail.nih.gov* for more information.

Hybrid T-Cell Receptors for the Development of Improved Vaccines

Description of Technology: Cancer is one of the leading causes of death in United States and it is estimated that there will be more than half a million deaths caused by cancer in 2006. A major drawback of the current chemotherapy-based therapeutics is the cytotoxic side-effects associated with them. Thus there is a dire need to develop new therapeutic strategies with fewer side-effects. Immuno-therapy has taken a lead among the new cancer therapeutic approaches. Adoptive immunotherapy is one of the most promising new therapeutic approaches that enhance the innate immunity of an individual to fight against a certain disease.

T cell receptors (TCR) are the proteins responsible for the T cell's ability to recognize infected or transformed cells. TCR consists of two domains, one variable domain that recognizes the antigen and one constant region that helps the TCR anchor to the membrane and transmit the recognition signal by interacting with other proteins.

The present invention involves the construction of hybrid anti-cancer TCR that is half mouse and half human. Functional analysis reveals that human TCR with a mouse constant region is significantly better than pure human TCR. This hybrid protein when put into human T cells makes these cells much better in recognizing cancer associated proteins. The hybrid protein can be used to improve the function of a T cell providing diagnostic and therapeutic applications in cancer and infectious diseases.

Development Status: The technology is in the pre-clinical stage, animal studies are complete, and a clinical protocol for a Phase I clinical trial for stage IV refractory melanoma is currently under review by the NIH IRB.

Inventors: Richard A. Morgan, Cyrille J. Cohen, Steven A. Rosenberg (NCI).

Patent Status: U.S. Provisional Application No. 60/796,853 filed 03 May 2006 (HHS Reference No. E–086–2006/0–US–01).

Relevant Publications:

1. CJ Cohen, Y Zhao, Z Zheng, SA Rosenberg, RA Morgan. Enhanced antitumor activity of murine-human hybrid T-cell receptor (TCR) in human lymphocytes is associated with improved pairing and TCR/CD3 stability. Cancer Res., in press.

2. MS Hughes, YY Yu, ME Dudley, Z Zheng, PF Robbins, Y Li, J Wunderlich, RG Hawley, M Moayeri, SA Rosenberg, RA Morgan. Transfer of a TCR gene derived from a patient with a marked antitumor response conveys highly active T-cell effector functions. Hum Gene Ther. 2005 Apr;16(4):457–472.

Licensing Status: This technology is available for licensing under an exclusive or non-exclusive patent license.

Licensing Contact: Michelle Booden, Ph.D.; 301/451–7337; *boodenm@mail.nih.gov*

Collaborative Research Opportunity: The NCI Surgery Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize hybrid T-cell receptors for the development of improved vaccines. Please contact Betty Tong at 301–496–0477; *tongb@mail.nih.gov* for more information.

Adoptive Immunotherapy With T Lymphocytes Engineered for Enhanced Survival

Description of Technology: Available for licensing is a composition, comprising genetically engineered lymphocytes, transduced to express elevated levels of cytokine proteins. This technology is useful for improving cellular adoptive immunotherapies to treat a range of infectious diseases and cancers.

Adoptive immunotherapy has repeatedly been shown to be useful in the treatment of patients with metastatic melanoma. However, clinical efficacy of this treatment is limited by the short-lived survival of the transferred, autologous, antigen-specific T cells. It would be desirable to genetically modify effector cells to provide not only enhanced effector cell survival, but also desired antigen specificity, and improved function, and safety. The current technology provides a method address this desire, by genetically modifying lymphocytes using retroviral vectors.

Specifically, isolated autologous T lymphocytes can be transformed with polynucleotides encoding endogenous cytokines, for example IL–7 or IL–15. IL–15-transduced lymphocyte cultures demonstrate prolonged in vitro persistence. In addition, T cells can be transduced to express not only cytokines but also T cell receptors to confer specificity for certain antigens. Recent data showed that human T lymphocytes engineered to express a murine anti-human p53 T cell receptor can recognize tumor cell lines, as well as fresh human tumors, and are able to kill p53-expressing human tumor cells.

Also provided in the invention are methods for treating patients with transformed lymphocytes as part of adoptive immunotherapy. Applications of this technology beyond cancer include the potential use of cytokine expressing cells in treating infectious and autoimmune diseases and vaccination.

Inventors: Steven A. Rosenberg *et al.* (NCI).

Publications:

1. L Gattinoni, SE Finkelstein, CA Klebanoff, PA Antony, DC Palmer, PJ Spiess, LN Hwang, Z Yu, C Wrzesinski, DM Heimann, CD Surh, SA Rosenberg, NP Restifo. Removal of homeostatic cytokine sinks by lymphodepletion enhances the efficacy of adoptively transferred tumor-specific CD8+ T cells. J Exp Med. 2005 Oct 3;202(7):907–912.

2. LX Wang, R Li, G Yang, M Lim, A O'Hara, Y Chu, BA Fox, NP Restifo, WJ Urba, HM Hu. Interleukin-7-dependent expansion and persistence of melanoma-specific T cells in lymphodepleted mice lead to tumor regression and editing. Cancer Res. 2005 Nov 15;65(22):10569–10577.

3. L Gattinoni, DJ Powell Jr, SA Rosenberg, NP Restifo. Adoptive immunotherapy for cancer: building on success. Nat Rev Immunol. 2006 May;6(5):383–393.

4. CJ Cohen, *et al.* Recognition of fresh human tumor by human peripheral blood lymphocytes transduced with a bicistronic retroviral vector encoding a murine anti-p53 TCR. J Immunol. 2005 Nov 1;175(9):5799–5808.

5. C Hsu, *et al.* Primary human T lymphocytes engineered with a codon-optimized IL–15 gene resist cytokine withdrawal-induced apoptosis and persist long-term in the absence of exogenous cytokine. J Immunol. 2005 Dec 1;175(11):7226–7234.

6. SA Rosenberg and ME Dudley. Cancer regression in patients with metastatic melanoma after the transfer of autologous antitumor lymphocytes. Proc Natl Acad Sci USA 2004 Oct 5;101 Suppl 2:14639–14645.

7. CA Klebanoff, *et al.* IL–15 enhances the in vivo antitumor activity of tumor-reactive CD8+ T cells. Proc Natl Acad Sci USA 2004 Feb 17;101(7):1969–1974.

8. K Liu and SA Rosenberg. Interleukin-2-independent proliferation of human melanoma-reactive T lymphocytes transduced with an exogenous IL–2 gene is stimulation dependent. J Immunother. 2003 May-Jun;26(3):190–201.

9. K Liu and SA Rosenberg. Transduction of an IL–2 gene into human melanoma-reactive lymphocytes results in their continued growth in the absence of exogenous IL–2 and maintenance of specific antitumor activity. J Immunol. 2001 Dec1;167(11):6356–6365.

Patent Status: U.S. Provisional Application No. 60/617,340 filed 08 Oct 2004 (HHS Reference No. E–340–2004/0-US–01); PCT Application No. PCT/US05/3640 filed 07 Oct 2005 (HHS Reference No. E–340–2004/2-PCT–01)

Licensing Status: Available for exclusive and non-exclusive licensing.

Licensing Contact: Michelle A. Booden, Ph.D.; 301/451–7337; *boodenm@mail.nih.gov*

Collaborative Research Opportunity: The NCI Surgery Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the clinical applications of T cell receptor technology. Please contact Steven A. Rosenberg, M.D., Ph.D. at 301–496–4164 for more information.

Dated: August 21, 2006.

Steven M. Ferguson,

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

[FR Doc. E6–14184 Filed 8–25–06; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed 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 the following 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 Cancer Institute Special Emphasis Panel, CA07–002, 008, 009, Application of Emerging Technologies for Cancer Research (STTR R41/R42), (SBIR R43/44), (R21/R33, R21, R33).

Date: October 18–19, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Bethesda Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: C. Michael Kerwin, PhD, MPH, Scientific Review Administrator, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd., Rm. 8057, Bethesda, MD 20892–8329. 301–496–7421. *kerwinm@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS).

Dated: August 17, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–7167 Filed 8–25–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings 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 Institute of Dental and Craniofacial Research Special Emphasis Panel; 07–07, Review R21.

Date: September 28, 2006.

Time: 11:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Raj K. Krishnaraju, PhD, MS, Scientific Review Administrator, Scientific Review Branch, National Inst of Dental & Craniofacial Research, National Institutes of Health, 45 Center Dr., Rm 4AN 32J, Bethesda, MD 20892. 301–594–4864. *kkrishna@nidcr.nih.gov.*

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel; 07–06, Review R03s, Ks.

Date: October 19, 2006.

Time: 10:30 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Raj K. Krishnaraju, PhD, MS, Scientific Review Administrator, Scientific Review Branch, National Inst of Dental & Craniofacial Research, National Institutes of Health, 45 Center Dr., Rm 4AN 32J, Bethesda, MD 20892. 301–594–4864. *kkrishna@nidcr.nih.gov.*

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel; 07–17, Review R01.

Date: October 19, 2006.

Time: 2 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Sooyoun (Sonia) Kim, MS, 45 Center Dr., 4An 32B, Division of Extramural Research, National Inst. of Dental & Craniofacial Research, National Institutes of Health, Bethesda, MD 20892. (301) 594–4827. *kims@email.nidr.nih.gov.*

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel; 07–08, Review of R21s.

Date: November 10, 2006.

Time: 2 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Yujing Liu, MD, PhD, Scientific Review Administrator, National Institute of Dental & Craniofacial Res., 45 Center Drive, Natcher Building, Rm. 4AN38E, Bethesda, MD 20892. (301) 594–3169. *yujing_liu@nih.gov.*

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel; 07–14, Review of R21.

Date: November 10, 2006.

Time: 3:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Yujing Liu, MD, PhD, Scientific Review Administrator, National Institute of Dental & Craniofacial Res., 45 Center Drive, Natcher Building, Rm. 4AN38E, Bethesda, MD 20892. (301) 594–3169. *yujing_liu@nih.gov.*

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel; 07–09, Review R21s.

Date: November 21, 2006.

Time: 2 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Yujing Liu, MD, PhD, Scientific Review Administrator, National Institute of Dental & Craniofacial Res., 45 Center Drive, Natcher Building, Rm. 4AN38E, Bethesda, MD 20892. (301) 594–3169. *yujing_liu@nih.gov.*