The annual reporting burden is as follows:

Estimated Number of Respondents: 250;
Estimated Number of Responses per Respondent: 1;

Average Burden Hours Per Response: .0.3674; and
Estimated Total Annual Burden Hours Requested: 91.85.

The annualized cost to respondents is estimated at: $5,218. There are no

A.12–1.—ESTIMATES OF HOUR BURDEN

<table>
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<th>Type of respondents</th>
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<th>Frequency of response</th>
<th>Average time per response</th>
<th>Annual hour burden</th>
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<td>Total</td>
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<td></td>
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<td>91.85</td>
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</table>

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.

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. Marion Danis, Department of Clinical Bioethics, Building 10, room 1C118, National Institutes of Health, Bethesda, MD 20892, or call non-toll-free number 301–435–8727 or e-mail your request, including your address to: mdanis@cc.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.

David K. Henderson,
Deputy Director, Warren G. Magnuson Clinical Center, National Institutes of Health.

Ezekiel J. Emanuel,
Director, Department of Clinical Bioethics, Warren G. Magnuson Clinical Center, National Institutes of Health.

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.

ADDRESS: 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.

Humanized Anti-Carcinoma CC49 Monoclonal Antibodies

Description of Technology: The technology describes the humanization of a murine anti-carcinoma antibody CC49 which has been shown to react with Tumor Associated Glycoprotein 72 (TAG–72), an antigen which is expressed on human breast, ovarian, colorectal, and other carcinomas.

The invention includes a new method of humanization of a rodent antibody which is based on grafting all the Complementarity Determining Residues (CDRs) of a rodent antibody onto a human antibody framework. Additionally, the method identifies Specificity Determining Residues (SDRs), the amino acid residues in the hypervariable regions of an antibody that are most critical for antigen binding activity and of rendering any antibody minimally immunogenic in humans by transferring the SDRs of the antibody to a human antibody framework. The resulting humanized antibodies, including CDR variants thereof (including a CH2 deleted version), are also embodied in the invention, as are methods of using the antibodies for therapeutic and diagnostic purposes.

Furthermore, these antibodies are suitable for radiolabeling for the application in radioimmunotherapy (RIT) based treatment of several cancers. Phase I results of radioimmunotherapy for ovarian cancer using 89Yttrium-CC49 murine monoclonal antibodies have shown promising results and confirms feasibility of the use of these antibodies for RIT. Promising pharmacokinetic data for the radiolabeled humanized antibodies in colon carcinoma xenograft models were recently published.

Applications and Modality

1. A humanized anti-cancer CC49 monoclonal antibody has been developed.
2. New methods of humanization of rodent antibodies have been identified.
3. The antibody(s) has been shown to react with Tumor Associated Glycoprotein 72 (TAG–72), an antigen which is expressed on human breast, ovarian, colorectal, and other carcinomas.
4. These antibodies are suitable for radiolabeling for the application in radioimmunotherapy (RIT) based treatment of several cancers.
5. These antibodies can be useful in diagnosis and treatment of several cancers.

Development Status: The technology is currently in the pre-clinical stage of development. Phase I results of
radioimmunotherapy for ovarian cancer using ⁹⁰Yttrium-CC49 murine monoclonal antibodies have shown promising results and confirms feasibility of the use of these antibodies for radioimmunotherapy (RTT).

**Inventors:** Syed V. Kashmiri (NCI), Eduardo A. Padlan (NIDDK), Jeffrey Schlon (NCI).

**Publications**

1. RD Alvarez *et al.* A Phase I study of combined modality ⁹⁰Yttrium-CC49 intraperitoneal radioimmunotherapy for ovarian cancer. CInCancer Res. 2002 Sep; 8(9):2806–2811.

**Patent Status**


**Licensing Availability:** Available for exclusive and non-exclusive licensing.

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

**Collaborative Research Opportunity:** The National Cancer Institute's Laboratory of Tumor Immunology and Biology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize anti-carcinoma antibodies. Please contact John D. Howes, Ph.D. at 301–435–3121 or howesj@mail.nih.gov for more information.

**Enhanced T-cell Activation by Costimulation: An Effective Immunotheraphy for Cancer and Infectious Diseases**

**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 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 present technology describes recombinant poxvirus vectors encoding at least three or more costimulatory molecules and 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® are 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 conjuction with TRICOM®. The antigens include but are not limited to carcinoembryonic antigen (CEA), prostate-specific antigen (PSA), and MUC–1.

The combination of CEA, MUC–1, and TRICOM® is referred to as PANVAC® and the combination of PSA and TRICOM® is referred to as PROSTVAC®.

**Licensing Availability:** The technology is available for exclusive and non-exclusive licensing in combinations and for different fields of use. Some potential licensing opportunities 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, PSA, and MUC–1;
3. PANVAC® and/or PROSTVAC®; and
4. Recombinant fowlpox-GM–CSF.

**Application(s) and Modality:** Vector-based TRICOM® (alone or with a transgene for a tumor antigen and/or an immunostimulatory molecule), PANVAC® and PROSTVAC® and combinations thereof can be a potential novel immunotherapeutic approach for the treatment of cancer and infectious diseases.

**Advantages**

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

**Development Status:** Phase I and Phase II results available for poxvirus recombinants containing transgenes for TRICOM®, CEA–TRICOM®, PANVAC®, and PROSTVAC®. Further clinical studies are ongoing for other combinations.

**Inventors:** Jeffrey Schlon (NCI) *et al.*

**Publications**

2. Kantoff PW GL, Tannenbaum SI, DeRaffele, Mitcham J, Moroziewicz D, Schlom J, and PROSTVAC®. Randomized, double-blind, vector-controlled study of targeted immunotherapy in patients (pts) with


Patent Status


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

Cooperative Research and Development Agreement (CRADA) Opportunity: 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:

1. Generate and characterize recombinant poxviruses expressing specific tumor-associated antigens, cytokines, and/or T-cell costimulatory factors.

2. Analyze the recombinant poxviruses containing these genes with respect to appropriate expression of the encoded gene product(s).

3. Supply adequate amounts of recombinant virus stocks for preclinical testing.


5. Submit Drug Master Files detailing the development, manufacture, and testing of live recombinant vaccines to support the NCI-sponsored INDs.

6. Supply adequate amounts of clinical grade recombinant poxvirus vaccines for clinical trials conducted at the NCI Center for Cancer Research (CCR), and

7. Provide adequate amounts of vaccines for extrapolated clinical trials through a clinical agreement with the Division of Cancer Treatment and Diagnosis, NCI.

NCI will:

1. Provide genes of tumor-associated antigens, cytokines and other immunostimulatory molecules for incorporation into poxvirus vectors,

2. Evaluate recombinant vectors in preclinical models alone and in combination therapies,
3. Conduct clinical trials of recombinant vaccines alone and in combination therapies, and
4. Provide Drug Master Files currently supporting the clinical use of the recombinant poxvirus vaccines.

If interested in the above described CRADA, please submit a statement of interest and capability to Kevin Chang, PhD, in the NCI Technology Transfer Center at changke@mail.nih.gov or 301–496–0477.


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

[FR Doc. E7–9541 Filed 5–16–07; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

National Center for Complementary and Alternative Medicine; 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 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 Center for Complementary and Alternative Medicine Special Emphasis Panel; Basic Science.

Date: June 11–12, 2007.

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

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Martina Schmidt, PhD, Scientific Review Administrator, Office of Scientific Review, National Center for Complementary, and Alternative Medicine, NIH, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, (301) 594–3456. schmidtma@mail.nih.gov.


Jennifer Spaeth,
Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–2427 Filed 5–16–07; 8:45 am]
BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

National Eye Institute; 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 the following meeting.

The meeting will be open 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 Eye Council.

Date: June 7, 2007.

Closed: 8:30 a.m. to 10:30 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Conference Room D, Bethesda, MD 20892.

Open: 10:30 a.m. to Adjournment.

Agenda: Following opening remarks by the Director, NEI there will be presentations by the staff of the Institute and discussions concerning Institute programs.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Conference Room D, Bethesda, MD 20892.

Contact Person: Lare Anne McNicol, PhD, Director, Division of Extramural Research, National Eye Institute, National Institutes of Health, Bethesda, MD 20892, (301) 451–2020.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHHS)