

to the Office of Management and Budget (OMB) a requests for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on October 21, 2002, page 64652 and allowed 60-days for public comments. No public comments were received. The purposes 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 implement on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Training Tomorrow's Scientists: Linking Minorities and Mentors Through the Web. Type of Information Collection Request: REVISION, OMB control number 0925-0475, Expiration Date 1/31/2003. **Need and Use of Information Collection:** This website allows federally-funded researchers supported by any of 27 Institutes and Centers of the NIH to submit an electronic form describing his or her research areas, as well as interests in mentoring minority students or junior faculty. The researcher's description is posted on the website for searching by interested minority applicants. Minority students or junior faculty search the website to identify researchers with whom they would like to work. The research projects in the database are located all over the country and involve cutting edge research activities by scientists funded through the Institutes and Centers of the NIH. These research projects range from studies of children to research on older adults, from laboratory research to field research, from social research to a combination of biological and behavioral research. Applicants conduct an electronic search using categories such as research areas of interest, desired geographic location of the researcher, and their level of education. The primary objective of the program is to ensure that, in the coming decades, a concentration of minority researchers will be available to address behavioral and social factors important in improving the public health and eliminating racial disparities. Increasing the number of minority scientists in the U.S. will expand our currently limited knowledge about the epidemiology and treatment of diseases in minority population. **Frequency of Response:** On occasion. **Affected Public:** Individuals or households. **Type of Respondents:** Students, Post-doctorals, Junior Faculty, and Principal Investigators. The annual

reporting burden is as follows: *Estimated Number of Respondents:* 50; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* 10 minutes; and *Estimated Total Annual Burden Hours Requested:* 8. There is no annualized cost to respondents. There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.

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. Dana Sampson, Program Analyst, OBSSR, OD, NIH, Building 1, Room 256, 1 Center Drive, Bethesda, MD 20892, or call non-toll-free number (301) 402-1146 or E-mail your request, including your address to: SampsonD@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: December 13, 2002.

John Jarman,

*Executive Officer, Office of the Director,
National Institutes of Health.*

[FR Doc. 02-32365 Filed 12-23-02; 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, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies 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.

Improved Non-Viral Mammalian Expression Vector

Gary Nabel, Zhi-yong Yang (NIAID/VRC).

DHHS Reference No. E-318-2002/0 filed 24 Sep 2002.

Licensing Contact: Carol Salata; 301/435-5018; salatac@od.nih.gov.

This invention provides an improved expression vector that generates a higher level of protein than vectors currently in use. The expression vector is unique in that it uses a specific translational enhancer in combination with specific enhancer/promoters to yield high levels of protein expression and enhanced immunogenicity for DNA vaccines. This is particularly important because the potency of these vaccines in humans is marginal and this type of improvement can increase the effectiveness of various DNA vaccines. The expression vector cassettes can be used in other gene based vaccines as well, or for production of recombinant proteins from eukaryotic expression vectors. The invention may be useful in the production of genetic vaccines and gene therapies for a wide variety of diseases, including cancer and viral diseases such as HIV.

Contiguous Capillary Separation and Electrospray Ionization Sources and Analytical Devices

George Janini *et al.* (NCI)

DHHS Reference No. E-307-2002/0
filed 21 Oct 2002

Licensing Contact: Dale Berkley; 301/
435-5019; berkleyd@od.nih.gov

The invention is a device that acts as an interface between micro-scale separation instruments and electrospray ionization (ESI) mass spectrometers (MS), thus facilitating the separation and MS characterization of almost any type of analyte such as proteins, peptides, and small molecules. The device may be used as an interface between ESI-MS and any micro-scale separation technology such as capillary zone electrophoresis (CZE) capillary electrochromatography (CEC), capillary isoelectric focusing (cIEF), capillary isotachopheresis (cITF), electrokinetic chromatography (EKC), and high performance liquid chromatography (HPLC). The invention integrates a separation column, an electrical junction and a spray tip on a single piece of fused silica capillary. This invention offers advantages over existing ESI-MS interfaces, including ease of fabrication, ruggedness and a true zero dead volume junction between the separation column and the ESI tip.

Methods and Devices for Intramuscular Stimulation of Upper Airway and Swallowing Muscle Groups

Christy Ludlow *et al.* (NINDS)

DHHS Reference No. E-181-2002/0
filed 27 Sep 2002

Licensing Contact: Dale Berkley; 301/
435-5019; berkleyd@od.nih.gov

The invention is a method and device that induces intramuscular stimulation of the extrinsic and intrinsic laryngeal musculature to improve swallowing and voice and upper esophageal sphincter opening in humans. The device may be used to augment airway protection in persons with swallowing problems (dysphagia) who are at risk of aspiration. This invention will assist those persons who have chronic long-standing dysphagia and have not been benefited from early rehabilitative efforts, putting them at chronic risk of developing life-threatening pneumonia because of repeated aspiration. Limiting the entry of food or liquids into the lungs while swallowing, which is the objective of this invention, can prevent aspiration. Patients at risk of aspiration pneumonia currently require enteric (tube) feeding, a costly method for sustaining nutrition and one that greatly reduces quality of life. The invention comprises three unique components for

preventing aspiration during swallowing for some persons now requiring enteric feeding: (1) Intramuscular implantation to produce two synergistic actions; (2) independent long term control of stimulation during swallowing by patients; and, (3) a unique system of combining indwelling intramuscular electrodes and controllers.

Assays for Assembly of Ebola Virus Pseudoparticles Relevant to Antiviral Therapy and Vaccines

Gary Nabel, Yue Huang (NIAID/VRC)

DHHS Reference No. E-090-2002/0
filed 12 Jul 2002

Licensing Contact: Carol Salata; 301/
435-5018; salatac@od.nih.gov

This invention relates to assays for the identification of compounds that inhibit assembly of NP, VP35, and VP24, or inhibit the glycosylation of NP, required for nucleocapsid formation for the use as anti-viral agents. The invention also relates to assays for the identification of compounds that block glycosylation of proteins having a glycosylation domain that is substantially homologous to a glycosylation domain of NP required for polymerization. The invention further relates to pseudoparticles for presentation of antigens or antigenic epitopes for immunogenic or vaccination purposes especially filovirus vaccines such as Ebola.

Dengue Tetraivalent Vaccine Containing a Common 30 Nucleotide Deletion in the 3'-UTR of Dengue Types 1, 2, 3, and 4

Stephen S. Whitehead (NIAID), Brian R.

Murphy (NIAID), Lewis Markoff

(FDA), Barry Falgout (FDA)

DHHS Reference No. E-089-2002/0
filed 03 May 2002

Licensing Contact: Carol Salata; 301/
435-5018; salatac@od.nih.gov

The invention relates to a dengue virus tetraivalent vaccine containing a common 30-nucleotide deletion (Δ 30) in the 3'-untranslated region (UTR) of the genome of dengue virus serotypes 1, 2, 3, and 4. The previously identified Δ 30 attenuating mutation, created in dengue virus type 4 (DEN4) by the removal of 30 nucleotides from the 3'-UTR, is also capable of attenuating a wild-type strain of dengue virus type 1 (DEN1). Removal of 30 nucleotides from the DEN1 3'-UTR in a highly conserved region homologous to the DEN4 region encompassing the Δ 30 mutation yielded a recombinant virus attenuated in rhesus monkeys to a level similar to recombinant virus DEN4 Δ 30. This established the transportability of the Δ 30 mutation and its attenuation

phenotype to a dengue virus type other than DEN4. The effective transferability of the Δ 30 mutation establishes the usefulness of the Δ 30 mutation to attenuate and improve the safety of commercializable dengue virus vaccines of any serotype.

A tetraivalent dengue virus vaccine containing dengue virus types 1, 2, 3, and 4 each attenuated by the Δ 30 mutation is being developed. The presence of the Δ 30 attenuating mutation in each virus component precludes the reversion to a wild-type virus by intertypic recombination. In addition, because of the inherent genetic stability of deletion mutations, the Δ 30 mutation represents an excellent alternative for use as a common mutation shared among each component of a tetraivalent vaccine.

VAC-BAC Shuttle Vector System

Bernard Moss, Arban Domi (NIAID)

DHHS Reference No. E-355-2001/0
filed 10 Apr 2002

Licensing Contact: Carol Salata; 301/
435-5018; salatac@od.nih.gov

This invention relates to a VAC-BAC shuttle vector system for the creation of recombinant poxviruses from DNA cloned in a bacterial artificial chromosome. A VAC-BAC is a bacterial artificial chromosome (BAC) containing a vaccinia virus genome (VAC) that can replicate in bacteria and produce infectious virus in mammalian cells.

The following are some of the uses for a VAC-BAC:

1. VAC-BACs can be used to modify vaccinia virus DNA by deletion, insertion or point mutation or add new DNA to the VAC genome with methods developed for bacterial plasmids, rather than by recombination in mammalian cells.

2. It can be used to produce recombinant vaccinia viruses for gene expression.

3. It can be used for the production of modified vaccinia viruses that have improved safety or immunogenicity.

Advantages of the VAC-BAC shuttle system:

1. VAC-BACs are clonally purified from bacterial colonies before virus reconstitution in mammalian cells.

2. Manipulation of DNA is much simpler and faster in bacteria than in mammalian cells.

3. Modified genomes can be characterized prior to virus reconstitution.

4. Only virus with modified genomes will be produced so that virus plaque isolations are not needed.

5. Generation of a stock of virus from a VAC-BAC is accomplished within a week rather than many weeks.

6. Multiple viruses can be generated at the same time since plaque purification is unnecessary.

Dated: December 13, 2002.

Jack Spiegel,

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

[FR Doc. 02-32348 Filed 12-23-02; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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Immunotherapy With In Vitro-Selected Antigen-Specific Lymphocytes After Nonmyeloablative Lymphodepleting Chemotherapy

Mark E. Dudley, Steven A. Rosenberg, John R. Wunderlich (NCI)
DHHS Reference No. E-275-2002/0-US-01 filed 06 Sep 2002
Licensing Contact: Jonathan Dixon; 301/435-5559; dixonj@od.nih.gov.

This invention discloses a novel method of treating cancer. The approach uses autologous T-cells, which are selected for their highly avid recognition of an antigen expressed by the cancer. In studies performed at the National Cancer Institute (NCI), this method has proven effective in promoting the regression of cancer in patients with metastatic melanoma.

The treatment of 13 patients at NCI resulted in tumor shrinkage of at least 50 percent in six of the 13, and several patients remain cancer free more than a year after treatment. All of the patients enrolled in this trial had been unresponsive to previous therapies including, surgery, radiation and chemotherapy. This method represents a step forward in the treatment of cancer and offers a clinically proven approach to effectively promote the regression of tumors. Not only may this method apply to a variety of cancers, but it may also be applicable in treating other diseases such as AIDS, immunodeficiency, or other autoimmunity for which immune effector cells can impact the clinical outcome.

Humanized Anti-TAG 72 CC49 for Diagnosis and Therapy of Human Carcinomas

Syed V. Kashmiri (NCI), Jeffrey Schlom (NCI), Eduardo Padlan (NIDDK)
DHHS Reference No. E-013-2002/0-US-01 filed 28 Jun 2002
Licensing Contact: Jonathan Dixon; 301/435-5559; dixonj@od.nih.gov

Tumor associated glycoprotein (TAG-72) is expressed on the cells of a majority of human carcinomas, including colorectal, gastric, pancreatic, breast, lung, and ovarian. The murine monoclonal antibody (mAb) CC49 specifically recognizes TAG-72 and has a higher affinity for TAG-72 than its predecessor, B72.3.

The present invention discloses new humanized variants of CC49 that have a higher binding affinity to TAG-72 than previous humanized variants. Identified as HuCC49V15 and HuCC49V14, these variants also retain low immunogenicity of variable regions using sera of patients vaccinated with murine CC49.

These variants have potential benefits for use in the detection and/or treatment of a range of human carcinomas. Certain fields of use may not be available. Please contact OTT for information regarding the availability of specific fields of use.

Identification of Potential Ovarian Cancer Tumor Markers and Therapeutic Targets

Dr. Amir Jazaeri *et al.* (NCI)
DHHS Reference No. E-310-2001/0-US-01 filed 13 Feb 2002
Licensing Contact: Catherine Joyce; 301/435-5031; joycec@od.nih.gov

Genes that are differentially expressed in cancerous ovarian tissue as compared to normal ovarian tissue were identified using microarray technology. This technique was used to characterize gene expression patterns in BRCA-1

associated tumors, BRCA-2 associated tumors, sporadic tumors and immortalized "normal" ovarian epithelial cells. As a result of this analysis, genes that are up-regulated in ovarian cancer were identified. Approximately two-thirds of the sequences identified were previously known genes, while approximately one-third were expressed sequence tags (ESTs), representing sequences that are cloned and identified but not yet characterized. Eighty-three (83) genes were over-expressed in 50% of all tumors and these over-expressed sequences may be used as markers for ovarian cancer and/or targets for therapy.

The above-mentioned invention is available for licensing on an exclusive or non-exclusive basis.

A Metastasis Suppressor Gene on Human Chromosome 8 and Its Use in the Diagnosis, Prognosis, and Treatment of Cancer

Naoki Nihei (NIEHS), J. Carl Barrett (NCI), Natalay Kouprina (NCI), Vladimir Larionov (NCI)
DHHS Reference No. E-238-2001/0-US-01 filed 21 Dec 2001
Licensing Contact: Matthew Kiser; 301/435-5236; kiserm@od.nih.gov

The subject technology is directed to a gene on human chromosome 8 that suppresses metastasis of prostate cancer. The gene has been shown to suppress the metastatic ability of rat prostate cancer and is down-regulated in human prostate cancers from metastatic foci. Embodiments of the technology include gene therapy to prevent the metastasis of human cancer, in particular prostate cancer, use of the gene as a clinical marker in the diagnosis and prognosis of cancer, in particular prostate cancer, and the development of small molecules that mimic the effect of the gene product.

The present invention provides an isolated or purified nucleic acid molecule consisting essentially of a nucleotide sequence encoding the metastasis suppressor gene located at p21-p12 on human chromosome 8, which has been named Tey 1, or a fragment thereof comprising at least 455 contiguous nucleotides.

Detection and Quantification of Cripto-1 in Human Milk Using ELISA

Caterina Bianco, David S. Salomon (NCI)
DHHS Reference Nos. E-290-2000/0-US-01 filed 26 Jan 2001 and E-290-2000/0-PCT-02 filed 23 Jan 2002 (PCT/US02/02225)
Licensing Contact: Brenda Hefti; 301/435-4632; heftib@od.nih.gov