

enrollment rate, and a 70 percent retention rate. The purpose of the proposed survey in this announcement, is to examine facilitators and barriers to long-term participation in observational studies by African-Americans. The findings will be incorporated with the input of the African-American

community, into the recruitment and retention plan of the Jackson Heart Study. *Frequency of Response:* One-Time. *Affected Public:* Individuals or households. *Type of Respondents:* Adults ages 35–84. The annual reporting burden is as follows: Estimated Number of Respondents: 580; *Estimated Number*

*of Responses per Respondent:* 1; *Average Burden Hours Per Response:* .4069; and *Estimated Total Annual Burden Hours Requested:* 236. There are no Capital costs to report. There are no Operating or Maintenance Costs to report.

#### ESTIMATE OF HOUR BURDEN

Type of response	Number of respondents	Frequency of response	Average time per response	Annual hour burden
Short Version .....	120	1	.0668	8
ARIC Participants .....	50	1	.2839	14
ARIC Drops Outs .....	50	1	.2839	14
Jackson Community .....	300	1	.3674	110
In-Depth Interview .....	60	1	1.5000	90
Total .....	580	.....	.....	236

**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 Dr. Charles R. MacKay, NIH Project Clearance Officer, 6701 Rockledge Drive, MSC 7730, Rockville, MD 20892-7730, or call non-toll-free number (301) 435-0978 or E-mail your request, including your address to: MacKayC@odrockm1.od.nih.gov.

**COMMENTS DUE DATE:** Comments regarding this information collection are

best assured of having their full effect if received by January 4, 1999.

Dated: November 23, 1998.

**Donald P. Christoferson,**

*Executive Officer, National Heart, Lung, and Blood Institute.*

[FR Doc. 98-32319 Filed 12-3-98; 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.

##### A Display Technique for Identifying LINE-1 Insertion Site Polymorphisms

*G Swergold, F Sheen (FDA)*

DHHS Reference No. E-285-97/1 filed 29 Sept 98 (claiming priority of U.S. Provisional 60/060,353 filed 29 Sept 97)

*Licensing Contact:* Charles Maynard, 301/496-7735 ext. 243

The invention is a novel method to detect frequent insertion site polymorphisms in the human genome. Much of the repetitive DNA of mammalian genomes consists of long interspersed sequences or elements (LINES). Typical mammalian genomes contain over 20,000 copies of one of these LINES called LINE-1. These sequences actually create new copies of themselves in new places in the genome, and contribute to the variation in DNA between individuals. The present invention is a powerful new method for the detection of LINE-1 insertion sites. This method allows the analysis of the DNA from an individual, yielding DNA fingerprint information as well as information useful for the understanding of genetic variation in a population.

##### Mice With A Fluorescent Marker For Interleukin-2 Gene Activation

*H Gu, M Naramura, R Hu (NIAID)*

DHHS Reference No. E-279-98/0  
*Licensing Contact:* Jaconda Wagner, 301/496-7735 ext. 284

A complex scheme of events unfolds during an immune response and involves a variety of cell types and soluble factors. New tools are constantly needed to assess this scheme of events and help tease apart the roles of accessory, helper and effector cells. A mutant mouse strain has been developed, and it was generated by

replacing the interleukin-2 (IL-2) gene with a cDNA encoding the green fluorescent protein (GFP) from *A. victoria*. This unique modification should allow researchers to better monitor the early stages of T cell activation because IL-2 is one of a few cytokines that naive resting T cells can produce during primary T cell antigen receptor (TCR) stimulation. An additional benefit of using IL-2 is that IL-2 production, unlike cytokines such as interferon-gamma and interleukin-four, is restricted to activated T cells. This would therefore increase the specificity of this model, and it should decrease the extensive manipulation of cells that is currently necessary and minimize invasive protocols. This invention could be used as a screening assay for substances of immune modulators by manufacturers of a variety of products. It could provide a valuable research tool for the discovery genes and their products that induce the production of IL-2. Additionally, various T cell clones derived from these mice can be used as the sensitive tool to screen even trace amounts of pathogens, such as bacteria, in food.

#### **Inhibitors Of Formation Of Transmissible Spongiform Encephalopathy-Associated Prion Protein By Porphyrins And Phthalocyanines**

*W Caughey, L Raymond, M Horiuchi, B Caughey (NIAID)* Serial No. 60/096,148, filed 11 Aug 98

*Licensing Contact:* George Keller, 301/496-7735 ext. 246

The current invention provides for certain tetrapyrroles that specifically inhibit the conversion of protease-sensitive prion protein (PrP-sen) to the abnormal protease-resistant form (PrP-res) without apparent cytotoxic effects. These compounds represent a new class of inhibitors of PrP-res formation that are a source of therapeutic agents for transmissible spongiform encephalopathies or prion diseases. For more information, see Caughey, W. et al. (1998) Inhibition of Protease-Resistant Prion Formation by Porphyrins and Phthalocyanines, *Proc. Natl. Acad. Sci. USA* 95, 12117-12122.

#### **Use Of Constitutive Transport Elements To Control The Host Range Of Retroviral Vectors**

*AL Ferris, SH Hughes (NCI)* Serial No. 60/094,535 filed 29 Jul 98

*Licensing Contact:* Richard Rodriguez, 301/496-7056 ext. 287

The major host range determinant for retroviruses and for retroviral vectors is the envelope glycoprotein. However

there is a second element, the constitutive transport element, or CTE, that also plays an important role in determining host range. In order to replicate, retroviruses must transport both spliced and unspliced RNAs from the nucleus to the cytoplasm. For simple retroviruses, transport of the unspliced RNA requires an interaction between the CTE—which is small element in the viral RNA—and host factors. The CTE of avian sarcoma/leukosis viruses (ASLV) does not function in mammalian cells. As a consequence ASLV, and vectors derived from ASLV, will not replicate in mammalian cells even if the host/virus system is modified so that the entry of the ASLV into mammalian cells is efficient. This invention demonstrates how this barrier to viral replication is overcome by introducing sequences from an amphotropic murine leukemia virus (MLV) into a modified ASLV vector. The resulting vector can replicate in mammalian cells if the host cell/vector system is designed to provide compatibility between the envelope of the virus and the receptor on the host cell. The resulting ASLV vector should be useful for experimental applications both in cultured cells and in animal models. In addition to being able to extend the host range of retroviruses by modifying their CTEs, it is also possible to restrict their host range. A modified MLV virus that replicates only in avian cells, not in mammalian cells has been developed. This virus can be used to develop a new generation of safer MLV-based vectors. Therefore, this invention provides the advantages of being able to restrict or extend the ability of retroviral vectors to replicate in defined hosts by manipulating their CTEs. This will be useful in the development of a new generation of retroviral vectors that are both safer and more useful than those currently available.

#### **Cloned Genomes Of Infectious Hepatitis C Virus And Uses Thereof**

*M Yanagi, J Bukh, S Emerson, R Purcell (NIAID)* Serial No. 09/014,416, filed 27 Jan 98

*Licensing Contact:* George Keller, 301/496-7735 ext. 246

The current invention provides nucleic acid sequences comprising the genomes of infectious hepatitis C viruses (HCV) of genotype 1a and 1b. It covers the use of these sequences, and polypeptides encoded by all or part of sequences, in the development of vaccines and diagnostic assays for HCV and the development of screening assays for the identification of antiviral

agents for HCV. Additional information can be found in Yanagi et al., (1997) *Proc. Natl. Acad. Sci., USA* 94, 8738-8743 and Yanagi et al., (1998) *Virology* 244, 151-172.

#### **Chemokine Variants And Methods Of Use**

*T Oravec, MA Norcross (FDA)* Serial No. 60/067,033 filed 01 Dec 97  
*Licensing Contact:* Carol Salata, 301/496-7735 ext. 216

This invention relates to a nucleotide and amino acid sequence of truncated RANTES (3-68) which is different from the wild type RANTES in two amino acid positions. CD26 is a leukocyte activation marker that possesses dipeptidyl peptidase IV (DPPIV) activity but whose natural substrates and immunological functions had not been previously defined. Several chemokines, including RANTES (regulated on activation, normal T expressed and secreted) are provided, which are substrates for human CD26. RANTES (3-68) retains the ability to stimulate CCR5 receptors and to inhibit the cytopathic effects of HIV-1. The invention provides methods for identifying compounds that affect DPPIV-mediated chemokine cleavage, methods for inhibiting HIV infection and treating individuals having or at risk of having HIV infection, methods for diagnosis and/or prognosis of individuals having a chemokine-associated disorder and methods for accelerating wound healing and angiogenesis, all based on the discovery of DPPIV-mediated cleavage of chemokines.

#### **Infectious Papillomavirus Pseudoviral Particles**

*DR Lowy, JT Schiller, RB Roden (NCI)* DHHS Reference No. E-032-96/1; PCT/US97/12115 filed 14 Jul 97, with priority to 17 Jul 96

*Licensing Contact:* Robert Benson, 301/496-7056 ext. 267

This invention describes pseudoviral particles of papillomavirus capsids encapsidating DNA useful for gene therapy and as vaccines. The pseudoviral particles are made by co-expressing the papillomavirus L1, L2 and E2 genes in a cell line along with a vector comprising the useful DNA and DNA containing E2 protein binding sites (E2BS). It is the discovery of the inventors that the presence of the E2BS containing DNA results in the encapsidation of the DNA. The encapsidated DNA can be a gene to replace a defective gene, or can encode an antigen, for gene therapy or immunization respectively. Since

papillomaviruses selectively multiply in epithelial cells, the capsids may be particularly useful for mucosal vaccines, and for delivering genes to epithelial tissues. The existence of many non-crossreacting serotypes of human papillomaviruses can be taken advantage of to eliminate the problem of immune rejection of a pseudoviral particle. The same gene or antigen encoding DNA can be incorporated in pseudoviral particles of different serotypes for multiple dosing. The inventors have demonstrated delivery of the neomycin resistance gene to mammalian cells with a BPV capsid encapsidating a vector consisting of the neomycin gene under control of a mammalian promoter and DNA containing E2 binding sites. Claimed are the pseudoviral particles, methods of making them, and methods of using them.

#### **Method of Inhibiting The Activity of an Intracellular Constituent**

*MJ Mulligan-Kehoe (NCI)*

U.S. Patent 5,702,892 issued 30 Dec 97; Serial No. 08/897,040 filed 18 Jul 97; Serial No. 09/096,889 filed 12 Jun 98

*Licensing Contract: Marlene Shinn, 301/496-7056 ext. 285*

Two combinatorial libraries of binding proteins have been engineered. The libraries were designed to genetically shuffle oligonucleotide motifs within the framework of the immunoglobulin heavy chain gene by random mutation of either the CDRI or CDRIII hypervariable regions. The Fd fragment of the heavy chain gene was then reconstructed such that it contained the randomized oligonucleotides in the hypervariable region, resulting in a collection of highly diverse sequences. The libraries of heavy chain proteins encoded by the array of mutated gene sequences potentially have all of the binding characteristics of an immunoglobulin while requiring only the heavy chain Fd protein.

The re-engineered heavy chain gene sequences were ligated into a M13-derived bacteriophage vector that permits expression of the binding proteins as fusion proteins with viral protein 8, which is expressed on the phage surface.

The claims of the patent application provide methods to screen the libraries, to identify the binding protein to a specific antigen and the gene for that specific protein, and to re-engineer the gene for intracellular expression in a eukaryotic cell. Inducible intracellular inactivation of glucose-6-phosphate dehydrogenase (G6PDH) has been

demonstrated by in vivo expression of a gene construct encoding a binding protein selected from one of the libraries and specific for G6PDH. Removal of induction restored the enzyme activity.

The libraries of binding proteins, the screening methods, and the methods of inhibiting intracellular components claimed in the patent application provide powerful potential tools for cellular and molecular biology by affording the capability of binding/inactivating any protein of choice.

#### **Amino Acid Sequencing Peptides and Methods for Their Use**

*DC Parmelee, S Sechi (NCI)*

U.S. Patent 5,589,397 issued 31 Dec 96; Serial No. 08/739,819 filed 30 Oct 96

*Licensing Contract: Manja Blazer, 301/496-7056 ext. 224*

The present invention provides a novel internal standard for amino acid sequencing which consist of a peptide containing at least two different unnatural amino acid residues, such as ornithine, norvaline, norleucine and  $\alpha$ -aminobutyric acid. The PTH-derivatives of these have retention times distinct from those of natural amino acids. This peptide can be sequenced simultaneously with an unknown peptide or protein without interfering with the analysis. Simultaneous sequencing of this standard provides information which allows for the determination of repetitive yields, lags, N-terminal blockage and discrimination between blank cycles caused by missed injection and blank cycles caused by faulty delivery of chemicals during the sequencing reactions.

Dated: November 30, 1998.

**Jack Spiegel,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer.*

[FR Doc. 98-32318 Filed 12-3-98; 8:45 am]

BILLING CODE 4140-01-M

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **National Institutes of Health**

##### **National Institute of Neurological Disorders and Stroke; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Neurological Disorders and Stroke Special Emphasis Panel.

*Date:* December 3, 1998.

*Time:* 2:00 PM to 3:00 PM.

*Agenda:* To review and evaluate contract proposals.

*Place:* NIH/NINDS, Federal Building, Room 9C10, 7550 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Phillip F. Wiethorn, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Activities, NINDS, National Institutes of Health, PHS, DHHS, Federal Building, Room 9C10, 7550 Wisconsin Avenue, Bethesda, MD 20892, 301-496-9223.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

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

Dated: November 30, 1998.

**LaVerne Y. Stringfield,**

*Committee Management Officer, NIH.*

[FR Doc. 98-32312 Filed 12-3-98; 8:45 am]

BILLING CODE 4140-01-M

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **National Institutes of Health**

##### **National Institute on Alcohol Abuse and Alcoholism; 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 Board of Scientific Counselors, NIAAA.

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 as indicated below in accordance