With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

III. Criteria for Members

Persons nominated for membership as a consumer representatives on the committee/panels must meet the following criteria: (1) Demonstrate ties to consumer and community-based organizations, (2) be able to analyze technical data, (3) understand research design, (4) discuss benefits and risks, and (5) evaluate the safety and efficacy of products under review. The consumer representative must be able to represent the consumer perspective on issues and actions before the advisory committee; serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and facilitate dialogue with the advisory committees on scientific issues that affect consumers.

IV. Selection Procedures

Selection of members representing consumer interests is conducted through procedures that include the use of organizations representing the public interest and consumer advocacy groups. The organizations have the responsibility of recommending candidates of the agency's selection.

V. Nomination Procedures

All nominations must include a cover letter, a curriculum vita or resume (that includes the nominee's office address, telephone number, and e-mail address), and a list of consumer or community-based organizations for which the candidate can demonstrate active participation.

Nominations will specify the advisory committee or panel(s) for which the nominee is recommended. Nominations will include confirmation that the nominee is aware of the nomination.

Any interested person or organization may nominate one or more qualified persons for membership as consumer representatives on the advisory committee/panels. Self-nominations are also accepted. Potential candidates will be required to provide detail information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of a conflict of interest. The nomination should specify the committee/panels of interest. The term of office is up to 4 years, depending on the appointment date.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: February 4, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9–2845 Filed 2–10–09; 8:45 am]

BILLING CODE 4160–01–S

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.

HTLV–II Vector and Methods of Use

Description of Technology: The invention hereby offered for licensing is in the field of vaccines and vaccine vectors. More specifically the invention provides compositions and methods of use of HTLV–II viral vector. The vector comprises at least a portion of the HTLV–II genome encoding the gag, pro, and pol genes and lacking all or a portion of the pX region. A heterologous gene is inserted within the deletion of the pX region. The gene of interest may encode all or a portion of a protein that corresponds to a viral protein of a foreign virus. The viral vectors thus constructed are useful for inducing immune response to the viral protein from the foreign virus. In particular the invention claims vaccines against HIV and SIV.

Applications: The technology can be used for DNA-based vaccines.

Advantages:

- Vaccines based on HTLV–II vectors have exhibited the capability to eliciting T cell response effectively. In particular they induce specific CD4+ and CD8+ T cell response. Antibody response to the HTLV–II vector is almost undetectable. The vector is infectious, but highly attenuated, with respect to the wild type HTLV–II. Desirably, the HTLV–II viral vector induces antibodies that can participate in Antibody-Dependent-Cell-Mediated Cytotoxicity (ADCC), a mechanism that enhances its effectiveness.
- Most of the T-cell vaccines developed for HIV are based on microbial vectors that have limited replication capacity and do not persist in the host. Such vaccines do not protect macaques from SIV infection and their ability to protect against high virus load is merely transient (approximately six months). They are perceived to elicit too ''small T-cell responses'' that expand ''too late''. In addition, few of these vectors target mucosal sites, the first portal of HIV entry. In contrast, an HTLV–II based vaccine is anticipated to infect macaques and replicate at very low level in lymphoid tissue and particularly in the gut which may enable them to maintain sufficient level of effectors CD8 memory cells to decrease early seeding of the virus, and sufficient level of central memory cells in lymph nodes that may limit the broadcasting of the virus at distal sites. These features make an HTLV–II based vaccine for HIV an excellent unique candidate to target mucosal tissues and provide long lasting mucosal immunity to HIV. In addition, the HTLV–II infects dendritic cells both in vivo and in vitro, and the HTLV–II infected dendritic cells have a mature phenotype, suggesting that HIV antigens expressed within dendritic cells could be effectively presented to the immune system.
- HTLV–II is a human retrovirus with no clear disease associations neither in healthy nor in HIV infected individuals.
- HTLV shares many biological and molecular characteristics of HIV, including routes of transmission, a T-cell tropism and gut tropism.
- Based on the above, it is believed that HIV vaccines based on HTLV–II vector will exhibit superiority compared to other vaccines in development.

Development Status: At the present only in vitro as well as animal (macaques) data that demonstrate the

proof of concept are available. The data indicates that an HTLV–II based vaccine could replicate in the appropriate body compartment and confer immunity in humans. The inventors continue to work on the development of this approach.

Market: In spite of major global efforts of more than 25 years in developing a vaccine against HIV/AIDS, such a vaccine is still not in existence but yet very much needed for the fight against the global epidemic of HIV/AIDS. The market for HIV/AIDS drugs is currently at the level of approximately $6 billion a year and is expected to grow to $13 billion by the year 2015. Should an effective vaccine be developed the market for such a vaccine may exceed this level. The instant technology may offer superiority to existence approaches in the area of HIV vaccines and thus a huge commercial opportunity for pharmaceutical/vaccine enterprises as well as a major contribution for global public health.

Inventors: Genoveffa Franchini, Izabela Bialuk, Vibeke Andresen, Shari Gordon, Valentina Cecchinato, Francis Ruscetti, Kathryn Jones (NCI).

Publications: Paper in preparation.

Patent Status: U.S. Provisional Application No. 61/081,994 filed 18 Jul 2008 (HHS Reference No. E–269–2008/0–US–01).

Related Technologies: RhCMV SIV vaccine (Picker *et al.*).

Licensing Status: The technology is available for exclusive or non-exclusive licensing.

Licensing Contact: Uri Reichman, Ph.D., MBA; 301–435–4616; *UR7a@nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute, Animal Models & Retroviral Vaccine Section, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize HTLV–II vectored HIV vaccines. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Adoptive Immunotherapy for Reestablishing HIV-specific Cytotoxic T-cell (CD8 T-cell) Function in HIV and AIDS Patients and Methods for Assessing the Reestablishment of CD8 T-cell Function

Description of Technology: This technology includes methods and compositions for rescuing or reestablishing the ability of HIV-specific, cytotoxic T-cells (CD8 T-cells) to proliferate and kill HIV-infected cells such as CD4 cells. Additionally, this invention provides a means for evaluating the ability of therapeutic vaccines or other therapies to reestablish CD8 T-cell function during HIV infection. As an immunotherapy, this technology involves treating peripheral blood mononuclear cells (PBMCs) from an HIV or AIDS patient to reestablish CD8 T-cell function and returning the treated cells to the patient. It is anticipated that this technology could provide an alternative to antiretroviral therapy (ART).

Background: This technology arose from research aimed at understanding why HIV infection does not progress in a subset of HIV-infected individuals, called long-term nonprogressors (LTNP). During the course of HIV infection HIV-specific CD8 T-cells from HIV progressors lose the ability to proliferate and kill HIV-infected cells using cytotoxins such as perforin and granzymes A and B. Unlike HIV progressors, it has been shown that CD8 T-cells from LTNP retain the ability to proliferate and use cytotoxins to kill HIV-infected cells. This technology provides a means for rescuing HIV-specific CD8 T-cell proliferation and cytotoxic functions in HIV progressors.

Applications:

- Treatment of HIV infection
- Assessing the effectiveness of therapeutic vaccines or other immune therapies

Advantages:

- Novel strategy for treating HIV infection
- Direct measure of the reestablishment of CD8 T-cell function
- Alternative to ART

Development Status: In vitro data available. Primate studies are underway.

Market:

- HIV therapeutics
- Immunotherapy and therapeutic vaccine development

Inventors: Mark Connors and Stephen Migueles (NIAID).

Publication: SA Migueles *et al.* Lytic granule loading of CD8+ T cells is required for HIV-infected cell elimination associated with immune control. Immunity. 2008 Dec 29;29(6):1009–1021.

Patent Status: U.S. Provisional Application No. 61/070,849 filed 27 Mar 2008 (HHS Reference No. E–146–2008/0-US–01).

Licensing Status: This invention is available for exclusive or non-exclusive licensing.

Licensing Contact: Sally Hu, Ph.D.; 301–435–5606, *HuS@mail.nih.gov.*

Collaborative Research Opportunity: The NIAID Office of Technology Development is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Richard Williams at 301–451–3522 for more information.

Humanized Monoclonal Antibodies That Specifically Bind Japanese Encephalitis Virus (JEV) and Their Use

Description of Technology: Japanese encephalitis virus (JEV) is the prototype virus of the Japanese encephalitis (JE) group belonging to the Flavivirus genus of the Flaviviridae family. Other members of the group include Kunjin virus, St. Louis encephalitis virus, and West Nile encephalitis virus (WNV). JEV is widely distributed in South Asia, Southeast Asia, and the Asian Pacific Rim. In recent years, JE epidemics have spread to previously unaffected areas, such as northern Australia, Pakistan, India and Indonesia. The JE outbreak in India during July to November of 2005 was the longest and most severe in recent years, affecting more than 5,000 persons and causing more than 1,000 deaths. It is estimated that JEV causes 35,000 to 50,000 cases of encephalitis, including 10,000 deaths and as many neurologic sequelae, each year. The wide geographical distribution and the existence of multiple strains, coupled with the high rate of mortality and residual neurological complications in survivors, make JEV infection an important public health problem. Until a JEV vaccine becomes generally available, passive immunization with potently neutralizing anti-JEV antibodies remains an attractive strategy for short-term prevention of and therapeutic intervention in encephalitic JEV infections.

From a panel of 11 Fabs recovered by different panning strategies, three highly potent neutralizing antibodies, termed Fabs A3, B2, and E3, which recognized spatially separated regions on the JEV virion were identified. These antibodies reacted with epitopes in different domains: The major determinant for Fab A3 was Lys179 (domain I), that for Fab B2 was Ile126 (domain II), and that for Fab E3 was Gly302 (domain III) in the envelope protein, suggesting that these antibodies neutralize the virus by different mechanisms. These three Fabs and derived humanized monoclonal antibodies (MAbs) exhibited high neutralizing activities against a broad spectrum of JEV genotype strains. In preclinical testing, the monoclonal antibodies of the technology significantly prolonged the average survival time compared to the control group, suggesting a therapeutic potential for use of MAb B2 in humans.

This application claims the antibodies described above, methods of preventing

and/or treating JEV with the antibodies, and diagnostics using the antibodies of the technology.

Application: Development of Japanese Encephalitis Virus (JEV) vaccines, therapeutics and diagnostics.

Development Status: Monoclonal antibodies have been synthesized and preclinical studies have been performed.

Inventors: Ana P. Goncalvez, Robert H. Purcell, Ching-Juh Lai (NIAID).

Publication: AP Goncalvez *et al.* Humanized monoclonal antibodies derived from chimpanzee Fabs protect against Japanese encephalitis virus in vitro and in vivo. J Virol. 2008 Jul;82(14):7009–7021.

Patent Status: U.S. Provisional Application No. 61/123,905 filed 10 Apr 2008 (HHS Reference No. E–142–2008/0–US–01).

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

Licensing Contact: Peter A. Soukas, J.D.; 301–435–4646; *soukasp@mail.nih.gov.*

Collaborative Research Opportunity: The NIAID Office of Technology Development is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize ''Humanized Monoclonal Antibodies that Specifically Bind Japanese Encephalitis Virus (JEV) and Their Use''. Please contact Percy Pan at 301–451–3523 for more information.

Sialostatin Mediation Controls Blood-Feeding Success of the Tick Ixodes scapularis

Description of Technology: This invention offers an environmentally friendly alternative to existing acaricides (pesticides), and relates to vaccines against tick bites and the pathogens that the ticks may transmit.

Bites from the nymphal stage of *Ixodes scapularis* are associated with Lyme disease transmission in disease-endemic areas of central and eastern US. *Ixodes scapularis* nymphs are the key vector stage implicated in Lyme disease transmission, mainly due to their small size that makes timely detection difficult. Guinea pig vaccination against sialostatin L2, a secreted *Ixodes scapularis* salivary protein, can confer nymphal recognition and protection against the tick. Increased rejection rates, prolonged feeding time, and inflammation were observed in the vaccine group, indicating that a protective host immune response was elicited. Moreover, anti-sialostatin L2 titers correlate with weight reduction of nymphs by the end of feeding. These studies suggest that an essential action of sialostatin L2 can be blocked by host humoral immunity.

Applications: Use of Sialostatin L2 in a multi-component vaccine to protect against tick bites, and the pathogens that the ticks may transmit.

Advantages:

- Sialostatin L2 as an anti-tick vaccine will target the vector and therefore confer protection against all the pathogens that may be transmitted by the vector.
- An environmentally friendly alternative to acaricides.

Development Status: The technology is currently in the pre-clinical stage of development.

Market: Tick-borne diseases have alarmingly increased over the past years worldwide, affecting both human and animal populations. Lyme borreliosis is the most common and prevalent vector-borne human illness throughout the northern hemisphere. In the U.S., Lyme disease cases are steadily on the rise, exceeding the 23,000 reported to the CDC in 2005; while in Europe, the estimated cases are more than 50,000, making it a growing public health problem. Apart from transmitting the Lyme agent, the same tick species, of the genus *Ixodes*, serve as vectors for a repertoire of other human disease pathogens, such as viruses that cause tick-borne encephalitis, protozoa that cause babesiosis, and bacteria that cause granulocytic anaplasmosis, Q-fever, and Mediterranean spotted fever.

Inventors: Michalis Kotsyfakis (NIAID), José M.C. Ribeiro (NIAID), Jesus G. Valenzuela (NIAID), John Andersen (NIAID), Jennifer Anderson (NIAID), *et al.*

Publications:

1. M Kotsyfakis *et al.* Cutting edge: Immunity against a ''silent'' salivary antigen of the Lyme vector Ixodes scapularis impairs its ability to feed. J Immunol. 2008 Oct 15;181(8):5209–5212.

2. M Kotsyfakis *et al.* Selective cysteine protease inhibition contributes to blood-feeding success of the tick Ixodes scapularis. J Biol Chem. 2007 Oct 5;282(40):29256–29263.

3. M Kotsyfakis *et al.* Antiinflammatory and immunosuppressive activity of sialostatin L, a salivary cystatin from the tick Ixodes scapularis. J Biol Chem. 2006 Sep 8;281(36):26298–26307.

Patent Status:

- U.S. Provisional Application No. 60/963,332 filed 02 Aug 2007 (HHS Reference No. E–289–2007/0–US–01).
- PCT Patent Application No. PCT/US08/09075 filed 25 Jul 2008 (HHS Reference No. E–289–2007/1–PCT–01).

Licensing Status: Available for licensing.

Licensing Contact: RC Tang, JD, LLM; 301–435–5031; *tangrc@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases/Laboratory of Malaria and Vector Research/Vector Biology Section is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize potential applications based on the above mentioned patent and in regard to the protection from tick bites and the pathogens they transmit. Please contact Charles Rainwater, NIAID/OTD at 301–435–8617/or *crainwater@niaid.nih.gov* for more information.

A Parameterized Model for Simulating Microarrays

Description of Invention: The current invention describes a simulation procedure in which several parameters can be used to model microarray image formation. Over 20 model parameters, each governed by a probability distribution, control the signal intensity, spot geometry, spot drift, background effects, and the many kinds of noise that affect microarray images as a result of the manner in which they are formed. In practice, a simulated microarray image is generated according to a number of defined parameters and can be compared to a known value. An imaging procedure is then applied to the simulated microarray image to generate observed values. The known values can then be compared to the observed values to evaluate the imaging procedure.

The model can be used to measure the performance of imaging procedures designed to measure the true intensity of spots on microarrays. Modeling and simulation of microarray image formation is a key to benchmarking various signal processing tools being developed to estimate cDNA signal spots. Using a model to describe the true signal intensity not only helps in evaluating these tools, but also facilitates the understanding of various process interactions. The simulation program has been used extensively in the design of the microarray image-analysis program used at the National Human Genome Research Institute (NHGRI). This has been done by testing the accuracy of the analysis program on simulated images exhibiting troublesome noise conditions and then tuning the program to achieve better results.

The simulation procedure can be incorporated into hardware/software for

ease of use. The levels of foreground noise, background noise, and spot distortion can be set, and algorithms can be evaluated under varying conditions.

Applications:

• Microarray imaging

• Evaluation of gene expression

Advantages:

• Efficient and accurate microarray signal analysis

• Improved detection of weak targets and improved local background estimation for microarray spots

Development Status: Late stage.

Inventors: Yidong Chen (NHGRI) *et al.*

Publication: Y Balagurunathan, ER Dougherty, Y Chen, ML Bittner, JM Trent. Simulation of cDNA microarrays via a parameterized random signal model. J Biomed Opt. 2002 Jul;7(3):507–523.

Patent Status: U.S. Patent No. 7,363,169 issued 22 Apr 2008 (HHS Reference No. E–089–2003/0–US–03).

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

Licensing Contact: Jeffrey A. James, PhD; 301–435–5474; *jeffreyja@mail.nih.gov*.

System for Synergistic Combination of Multiple Automatic Induction Methods and Automatic Re-Representation of Data

Description of Invention: The present application describes a unique prototype of an advanced framework which relates to the field of multidimensional data mining, machine learning, and analysis that has been named COEV (for COEVolutional). COEV synergistically combines different methods of statistical analysis, neural networks, decision trees and genetic algorithms for the resolution of data queries. COEV automatically determines the optimal methods and data representations to apply at each step of inquiry and, as a result, can provide outcomes that are significantly more accurate than can be achieved by use of any one methodology alone. The invention uses an evolutionary learning technology to improve predictive outcomes with continued use. COEV is designed to advance the accuracy, flexibility, speed and ease of use of advanced data analysis technologies.

Characteristics of problems that are appropriate for the application of the COEV method are: (1) Appropriate for machine learning, in that there is a well-defined set of input variables and a clear prediction target; (2) difficult for traditional methods, and where a modest improvement in accuracy over existing machine learning methods (*e.g.*, neural networks) would be significant; (3) there is a large amount of training data, ideally thousands of cases.

Possible application areas of interest include the analysis of high-throughput screening data for pharmaceutical discovery, detecting patterns of fraud in insurance claims, or automating screening of medical images.

This invention requires further R&D and testing to make it a practical system for widespread use.

Applications:

• Machine learning

• High throughput screening analysis for pharmaceutical, biotechnology, and other industries

Advantages:

• More accurate interpretation and analysis of complex data networks

• Improved predictive outcomes with continued use (evolutionary learning)

Development Status: Early stage.

Inventors: Lawrence Hunter (NLM).

Patent Status: U.S. Patent No. 6,449,603 issued 10 Sep 2002 (HHS Reference No. E–118–1996/0–US–03).

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

Licensing Contact: Jeffrey A. James, PhD; 301–435–5474; *jeffreyja@mail.nih.gov*.

Computational Analysis of Nucleic Acid Information Defines Binding Sites

Description of Invention: Many approaches to determine whether a nucleotide change is a benign polymorphism or is associated with a genetic disease rely on sequence comparisons of a substantial number of individuals. This invention embodies a computational method that is able to predict whether a nucleotide change will have a deleterious effect. The claims of this invention relate to a computer program which has the novel feature in that it is designed to calculate the relative importance of a given nucleotide change. This program is unique in that it is capable of predicting the effect that a given nucleotide change would have on a particular sequence such as a known binding site. The method has been successfully applied to predicting the effects of changes at human splice junctions.

Further information is available at *http://www.ccrnp.ncifcrf.gov/~toms/walker/index.html*.

Applications:

• Predictive outcomes for genetic mutations

• Biomedical research

Development Status: Late stage.

Inventors: Thomas D. Schneider (NCI) *et al.*

Patent Status: U.S. Patent 5,867,402 issued 02 Feb 1999 (HHS Reference No. E–080–1995/0–US–01).

Licensing Status: Available for non-exclusive licensing.

Licensing Contact: Jeffrey A. James, PhD; 301–435–5474; *jeffreyja@mail.nih.gov*.

Dated: January 30, 2009.

Richard U. Rodriguez,

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

[FR Doc. E9–2820 Filed 2–10–09; 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 any 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.

Constructs for Measuring Activated Arf5 in Cells

Description of Technology: Scientists at the National Institutes of Health have developed a series of fusion protein constructs that can quantify the levels of activated Arf5 in cells. Arf5 is a member of the Arf family of GTP binding proteins and is an important regulator of intracellular trafficking and actin-mediated cell motility. Arf family members have been implicated to play a role in the spread of cancer (metastasis) and in the movement of cancer cells into healthy tissues (invasion). The constructs are DNA sequences of various portions of the carboxyl-terminal end of the Rab11-