

attitudes and behaviors by the mass media.

Frequency of Response: The revised NSPY data collection will continue over

a four-year period, ending in June 2003. Each data collection wave will last approximately 6 months. *Affected public:* Individuals and households.

Type of Respondents: Children and parents. The annual reporting burden, which will drop substantially from the original design, is as follows:

RESPONDENT AND BURDEN ESTIMATE

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total burden hours requested	Estimated annualized burden 1/1/01–5/31/02
Revised National Survey of Youth and Parents (Baseline 1/1/01–5/31/01)					
Screener Respondent	15,498	1	.06	930	¹ 620
Youth 9–11	738	1	.60	443	¹ 295
Teens 12–18	1,189	1	.73	868	¹ 579
Parents	1,369	1	.92	1,259	¹ 840
National Survey of Parents and Youth (Longitudinal 1/1/01–5/31/02)					
Screener Respondent	4,739	1.2	.06	341	³ 227
Youth 9–11	1,403	1.2	.60	1,010	³ 673
Adolescents 12–18	4,553	1.2	.90	3,934	³ 2,622
Parents	4,334	1.2	.90	4,680	³ 3,120
Total	² 33,823		.26	13,465	8,976

¹ Interviewing of revised NSPY baseline respondents begins 1/01; earlier baseline data collected from 11/99–12/00.

² Some number of screener respondents are later also selected for a parent interview. The exact overlapping proportion cannot be estimated at this time.

³ Follow-up of NSPY respondents from the earlier baseline data collected (11/99–12/00) begins 1/01.

There are no Capital Costs to report. There are no Operating or Maintenance Costs to report. Because of the sensitivity of collecting data from families in households involving children as young as 9 years old, and the importance of minimizing costs for repetitive, return visits to obtain respondent cooperation, IDA provides a reasonable cost incentive to reimburse respondents for their time, as approved by OMB.

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 revision in the data collection 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 revision, 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 Susan David, Project Officer; Division of Services, Epidemiology and Prevention Research, National Institute on Drug Abuse, Room 5153, MSC 9589, 6001 Executive Blvd., Bethesda, MD 20892–9589; or call non-toll-free number (301) 443–6504; or fax to (301) 443–2636; or email your request, including your address, to: Sdavid@nida.nih.gov.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before December 18, 2000.

Dated: October 2, 2000.

Laura Rosenthal,

Executive Officer, NIDA.

[FR Doc. 00–26584 Filed 10–16–00; 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.

Virus-Like Particles as Unlinked Adjuvants

John Schiller, Bryce Chackerian, Joseph Lee, Douglas Lowy (NCI), DHHS Reference No. E–231–00/0 filed 20 Jul 2000.

Licensing Contact: Peter Soukas; 301/496–7056 ext. 268; e-mail: soukasp@od.nih.gov

This invention claims immunostimulating or vaccine compositions in which non-infectious virus-like particles (VLPs) serve as unlinked adjuvants. Co-administration of VLPs with an antigen enhances induction of high titer IgG antibodies to self or foreign antigens and promotes T cell responses to foreign antigens. The

VLP-target antigen combination can be administered alone or with a traditional adjuvant. The VLPs of the current invention are contemplated to comprise capsid protein(s) of a virus assembled into a shell resembling a virion, but not containing pathogenic viral DNA or RNA. The VLPs are unlinked, rather than physically linked to the antigen because this may reduce the manufacturing complexity of the vaccine. Unlinked VLP adjuvants, for example papillomavirus VLPs, of the invention have a number of advantages: (1) They are non-inflammatory in humans, (2) are potent at amplifying IgG antibody responses to self antigens, (3) induce a pronounced Th1 type of T cell response, and (4) may provide two-fold protection, against the virus corresponding to the VLP type, as well as against the disease associated with the other component in the VLP-target antigen combination.

System and Method for Representing Knowledge in a Distributed System

Stephen J. Shaw (NCI), Serial No. 09/470,684 filed 23 Dec 1999.
Licensing Contact: Dale Berkley; 301/496-7735 ext. 223; e-mail: berkleyd@od.nih.gov

This invention relates to a knowledge base (KB) system for storing data in a computer system. More specifically, this invention relates to systems and methods for representing, manipulating, and displaying knowledge consisting of categories, entities and relationships stored in a plurality of databases. The invention contemplates providing a user-friendly computer-based distributed system of databases which enables its users to create, use and share a knowledge base of information consisting of diverse entities related to each other by semantically meaningful links. The system generates a knowledge base that allows individuals to store information on a virtually unlimited range of entities. Due to its design as a distributed system, it is well suited to preserve the autonomy and portability of data belonging to each individual and workgroup, while maintaining links of that data to publicly available data elsewhere in the system and even links to information on entities external to the system. Diverse strategies are employed to simplify the implementation and use of the system. Some unique features of this software-based invention are: (1) The ability to handle any number of conceptually distinct categories of items (such as people, events, institutions, tasks, concepts, processes, document types); (2) tools for creating relationships between any two or more objects, with the ability to categorize

types of relationships and decide which categories they apply to; (3) use of parent-child relationships to organize, view and navigate information; (4) flexibility in adding diverse categories of objects and relationships, while maintaining a simple underlying data structure and programming environment; and (5) the ability to view complex relationships in flexible and informative ways; (6) tools for managing names which are indispensable for finding the relevant objects; and (7) efficient ways to search information and filter retrievals to limit to relevant information.

Peptides that Stabilize Protein Antigens and Enhance Presentation to CD8+ T Cells

Roger Kurlander, Elizabeth Chao, Janet Fields (CC), DHHS Reference No. E-172-99/0 filed 06 Dec 1999.
Licensing Contact: Peter Soukas; 301/496-7056, ext. 268; e-mail: soukasp@od.nih.gov

This invention relates to compositions and methods for stabilizing an antigen against proteolytic degradation and enhancing its presentation to CD8+ cells. The invention claims "fusion agents," isolated molecules comprising a hydrophobic peptide joined to an epitope to which a CD8+ T cell response is desired. Also claimed in the invention are the nucleic acid sequences that encode the fusion agents.

Recently, there has been great interest in developing vaccines to induce protective CD8+ T cell responses, however, there are practical obstacles to this goal. Although purified antigenic peptides are effectively presented *in vitro*, introduced in a purified form they often do not stimulate effective T cell responses *in vivo* because the antigens are insufficiently immunogenic and too easily degraded. Adjuvants or infectious "carriers" often can enhance these immune responses, however, these added agents can cause unacceptable local or systemic side effects. The present invention increases antigen stability and promotes *in vivo* responses in the absence of an adjuvant or active infection.

The invention describes three variants of lemA, an antigen recognized by CD8+ cells in mice infected with *Listeria monocytogenes*. The antigenic and stabilizing properties of lemA can be accounted for by the covalent association of the immunogenic aminoterminal hexapeptide with the protease resistant scaffolding provided by amino acids 7 to 33 of the lemA sequence (lemA₍₇₋₃₃₎). Variants t-lemA, and s-lemA bearing an antigenic sequence immediately preceding

lemA₍₇₋₃₃₎, and lemS containing an immunogenic sequence immediately after lemA₍₇₋₃₃₎, each induce a CD8+ T cell response and protect the crucial immunogenic oligopeptide from protease degradation. The site of antigen insertion relative to lemA₍₇₋₃₃₎ can influence antigen processing by preferentially promoting processing either in the cytoplasm or endosomal compartment. Therefore, several embodiments of the invention involve the construction of antigen processing protein molecules and their methods of use. Alternatively, a DNA sequence coding lemA₍₇₋₃₃₎ may be inserted at an appropriate site to enhance the immunogenicity of the antigenic element coded by a DNA vaccine. In sum, this invention is an attractive, nontoxic alternative to protein/adjuvant combinations in eliciting CD8 responses *in vivo* and a useful element for enhancing the efficiency with which products coded by DNA vaccines are processed and presented *in vivo*. Because lemA₍₇₋₃₃₎ is particularly effective in protecting oligopeptides from proteases, this invention may have particular usefulness in enhancing local T cell at sites such as mucosal surfaces where there may be high proteolytic activity.

For more specific information about the invention or to request a copy of the patent application, please contact Peter Soukas at the telephone number or e-mail listed above. Additionally, please see a related article published in the Journal of Immunology at: 1999;163:6741-6747.

Major Neutralization Site of Hepatitis E Virus and Use of this Neutralization Site in Methods of Vaccination

Darren Schofield, Suzanne U. Emerson, Robert H. Purcell (NIAID), DHHS Reference No. E-043-00/0 filed 01 Dec 1999.
Licensing Contact: Carol Salata; 301/496-7735 ext. 232; e-mail: salatac@od.nih.gov

Hepatitis E is endemic in many countries throughout the developing world, in particular on the continents of Africa and Asia. The disease generally affects young adults and has a very high mortality rate, up to 20%, in pregnant women. This invention relates to the identification of a neutralization site of hepatitis E virus (HEV) and neutralizing antibodies that react with it. The neutralization site is located on a polypeptide from the ORF2 gene (capsid gene) of HEV. This neutralization site was identified using a panel of chimpanzee monoclonal antibodies that are virtually identical to human antibodies. Since this neutralization site

is conserved among genetically divergent strains of HEV, the neutralizing monoclonal antibodies may be useful in the diagnosis, treatment and/or prevention of hepatitis E. Furthermore, immunogens that encompass this neutralization site may be used in vaccination to effectively prevent, and/or reduce the incidence of HEV infection. Polypeptides containing this neutralization site may be useful in evaluating vaccine candidates for the production of neutralizing antibodies to HEV.

Viral Glycoprotein Subunit Vaccine

Richard Compans, Ranjit Ray, U.S. Patent 4,790,987 issued 13 Dec 1988.
Licensing Contact: Peter Soukas; 301/496-7056 ext. 268; e-mail: soukasp@od.nih.gov

The present invention relates to a vaccine composition useful in the prevention of virus-caused disease comprising as its active agent at least one immunogenically effective amount of immunogenic viral envelope glycoprotein complexed with a lipid. These subunit vaccine compositions are useful for the prevention of viral infections including influenza virus, parainfluenza virus, herpes virus, paramyxoviruses, rabies virus, and human T-cell lymphotropic viruses. The patent also discloses a method for preparing the vaccine compositions. A novel feature of the invention is the utilization of a dialyzable detergent for solubilization of the active component, which allows a relatively simple purification process on a large scale. Thus, these vaccines are easier to prepare than other glycoprotein subunit vaccines and retain their antigenicity to a greater extent than formalin-inactivated subunit vaccines.

Dated: October 5, 2000.

Jack Spiegel,

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

[FR Doc. 00-26585 Filed 10-16-00; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; 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 Center for Research Resources Special Emphasis Panel Comparative Medicine.

Date: October 24, 2000.

Time: 3 pm to 4 pm.

Agenda: To review and evaluate grant applications.

Place: Office of Review, National Center for Research Resources, 6705 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Sybil A. Wellstood, PhD, Scientific Review Administrator, Office of Review, National Center for Research Resources, 6705 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892-7965, 301-435-0814.

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. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333; 93.371, Biomedical Technology; 93.389, Research Infrastructure, National Institutes of Health, HHS)

Dated: October 5, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00-26569 Filed 10-16-00; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; 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 Center for Research Resources Special Emphasis Panel, Comparative Medicine.

Date: October 27, 2000.

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

Agenda: To review and evaluate grant applications.

Place: Office of Review, National Center for Research Resources, 6705 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Sybil A. Wellstood, PhD, Scientific Review Administrator, Office of Review, National Center for Research Resources, 6705 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892-7965, 301-435-0814.

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. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333; 93.371, Biomedical Technology; 93.389, Research Infrastructure, National Institutes of Health, HHS)

Dated: October 4, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00-26573 Filed 10-16-00; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; 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 Human Genome Research Institute Special Emphasis Panel.

Date: October 27, 2000.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.