intrinsic reasons for choosing to donate blood, as well as external reasons for choosing to donate blood. Donors who do not initially respond to the mail survey will be given the opportunity to complete the survey on a secured website. Comparisons will be made between one-time donors and repeat donors will be premise that repeat donors may have a stronger altruistic impetus for donating than donors who donate less frequently. Donors will be asked about the donation experience, the context in which he/she first donated blood, and questions addressing accessibility to donate. Using the Self-Report Altruism Scale, respondents will rate themselves based on other personal behaviors that are considered to exhibit social responsibility and/or altruism. Additionally, the study will examine possible barriers to donation, such as inconvenience, discomfort, and confidentiality, among donors who have not donated recently. With the majority of the blood supply coming from committed, repeat donors, information regarding why an individual decides to donate, and more importantly, what motivates them to come back, will provide valuable insight on possible strategies to encourage increased donation frequency among the current blood donor population. It is also important to gain perspective on why only 50% of first time donors return to donate again. Without successful recruitment of new regular donors it is impossible to sustain the blood supply and availability. Assessment of possible barriers to donation will provide areas for focusing improvement in the blood donation process. Blood availability continues to be one of the most serious problems facing the healthcare industry and was recently compounded by new Food and Drug Administration regulations regarding deferring donors who had traveled to or lived in the United Kingdom for a cumulative period of 6 months between 1980 and 1996. Data from this survey will provide a valuable perspective for devising strategies to increase blood donation the U.S. These data will be invaluable to NHLBI, FDA, and other government agencies in helping formulate policy for ensuring Americans that safe blood is available when needed. *Frequency of Response:* Once. *Affected Public:* Individuals. *Type of Respondents:* Adult Blood Donors. The annual reporting burden is as follows: *Estimated Number of Respondents:* 30,000; *Estimated Number of Respondents per Respondent:* 1; *Average Burden Hours Per Response:* 0.25; and *Estimated Total Annual Burden Hours Requested:* 7,500. The annualized cost to respondents is estimated at: $112,500 (based on $15 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Type of respondents	Estimated number of respondents	Estimated number of respondents per respondent	Average burden hours per response	Estimated total annual burden hours requested
Adult Blood Donors	30,000	1	0.25	7,500

Request for Comments

Written comments and/or suggestions from the public and affected agencies should address 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 approprated automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received on or before July 30, 2001.

FOR FURTHER INFORMATION CONTRACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. George J. Nemo, Group Leader, Transfusion Medicine, Scientific Research Group, Division of Blood Diseases and Resources, NHLBI, NIH, Two Rockledge Center, Suite 10042, 6701 Rockledge Drive, MSC 7950, Bethesda, MD 20892-7950, or call (301) 435-0075, or e-mail your request to: *nemog@nih.gov.*

Dated: May 17, 2001.

Donald Christoferson,

Executive Officer, NHLBI.

[FR Doc. 01–13344 Filed 5–25–01; 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.

Ocular Therapeutic Agent Delivery Devices And Methods

Michael R. Robinson (NEI), Karl G. Csaky (NEI), Peng Yuan (NEI), Cynthia Sung (EM), Robert B. Nussenblatt (NEI), Janine A. Smith (NEI)

Serial No. 09/808,149, filed Mar. 15, 2001

Licensing Contact: Dale Berkley; 301/496–7735 ext. 223; e-mail: berkleyd@od.nih.gov

The invention is directed to ocular implant devices for the delivery of therapeutic agents to the eye in a controlled and sustained manner. Implants suitable for either subconjunctival or intravitreal placement are the subject of the invention. These implants permit

continuous release of therapeutic agents into the eye over specified periods of time, which can be weeks, months or years. In one aspect of the invention a therapeutic agent is included in both an inner core or pellet and an exterior composite matrix layer to provide a dual mode release of the therapeutic agent. That is, a loading dose is initially delivered to the eye by the matrix layer followed by a transition in release rate to a relatively steady maintenance dosage that is sustained over a prolonged period of time. In another aspect of the invention, methods for making and using the implants are described. The time-dependent delivery of one or more drugs to the eye by this invention makes it possible to maximize the pharmacological and physiological effects of the eye treatment for human and veterinary applications.

Vessel Surface Reconstruction with a Tubular Deformable Model

Yim et al. (CC)
DHHS Reference No. E–202–00/1, filed Feb 15, 2001
Licensing Contact: Dale Berkley; 301/496–7735 ext. 270; e-mail: berkleyd@od.nih.gov

The invention is a method for modeling a carotid or renal artery to measure stenosis from 3D angiographic data that may otherwise exhibit limited image resolution and contrast. The method reconstructs vessel surfaces from 3D angiographic data using a deformable model that employs a tubular coordinate system. Vertex merging is incorporated into the coordinate system to maintain even vertex spacing and to avoid problems of self-intersection of the surface. This method produces reconstructed surfaces that have a realistic smooth appearance and accurately represent vessel shape. The method allows for an objective evaluation of vessel shape and may improve the precision of shape measurements from 3D angiography.

User Friendly Integrated Database for the Management of Animal Study Proposals

Antonia F. Calzone (NIAAA), Etienne Lamoreaux (NIAAA), Karen Montijo (NIDDK)
DHHS Reference No. E–215–00/0
Licensing Contact: Dale Berkley; 301/496–7735 ext. 223; e-mail: berkleyd@od.nih.gov

The invention is a set of templates written in FileMaker-Pro™ script that provides a convenient integrated database management system for tracking the care and disposition of laboratory animals. This software is a multifunction program that meets the needs of facility veterinarians, animal facility managers, and animal care personnel with respect to in-house records keeping and federal reporting requirements. The invention builds on the framework of the FileMaker Pro™ software, and results in a database system that stores information pertinent to all current Animal Study Proposals (ASPs). This design permits users to access the data from a networked centralized Windows NT based server using either a Macintosh or IBM compatible workstation. The invention comprises features that facilitate the day-to-day management of the animal facility as well as powerful information storage capabilities.

Identification of New Malaria Parasite Erythrocyte Binding Protein (BAEBL) that Binds to Human Red Cells

Ghislaine D. Mayer, Louis H. Miller (NIAID)
DHHS Reference No. E–328–00/0, filed Apr 03, 2001
Licensing Contact: Carol Salata; 301/496–7735 ext. 232; e-mail: salatac@od.nih.gov

Malaria is endemic in many parts of the world, particularly in tropical regions such as Asia, Central America and South America. Recent estimates of the number of cases of malaria worldwide are between five hundred million and one billion. There are approximately two to three hundred million new cases of malaria each year and malaria causes a minimum of one million deaths each year. This invention relates to the identification and characterization of the binding specificity of BAEBL, a novel Plasmodium falciparum erythrocyte binding ligand that interacts with human erythrocytes in a sialic acid dependent manner. This novel Plasmodium falciparum erythrocyte binding ligand is unique and quite distinct from previously described Plasmodium falciparum erythrocyte binding proteins EBA–175. BAEBL may be used as a malaria vaccine to block human red cell recognition and invasion.

Attenuated Host-Range Restricted Dengue Viruses Derived by Site-Directed Mutagenesis of the Conserved 3'-Stem and Loop Structure in Genomic RNA for Use as Vaccines

Lingling Zeng, Lewis Markoff (CBER/FDA)
DHHS Reference No. E–067–98/2, filed Mar 02, 2001
Licensing Contact: Carol Salata; 301/496–7735 ext. 232; e-mail: salatac@od.nih.gov

Although flaviviruses cause a great deal of human suffering and economic loss, there is a shortage of effective vaccines. The present invention is directed toward vector stage replication-defective flaviviruses that are replication-defective in mosquito vectors that transmit them to humans. The replication-defective flaviviruses of the present invention demonstrate a limited ability to replicate in the vector organisms that transmit flaviviruses from one host to another. More specifically, the present invention is directed toward the construction and propagation of flaviviruses that possess 3'-noncoding regions altered in such a way as to prevent or severely limit viral reproduction in a vector organism. Not only is the dengue 1 mutant replication defective in mosquitoes, but it is also attenuated and immunogenic in monkeys. Moreover, it protects against challenge, thus it has strong potential as a dengue vaccine.

A Chimeric Protein Comprising Non-Toxic Pseudomonas Exotoxin A and Type IV Pilin Sequences

David FitzGerald (NCI)
DHHS Reference No. E–283–00/0, filed Dec 21, 2000
Licensing Contact: Carol Salata; 301/496–7735 ext. 232; e-mail: salatac@od.nih.gov

This invention provides candidate chimeric vaccines that generate antibodies which interfere with adherence of Pseudomonas aeruginosa exotoxin A to epithelial cells and neutralize the cytotoxicity of exotoxin A. This invention specifically relates to a chimeric protein wherein key sequences from a Type IV pilin protein are inserted into a non toxic version of Pseudomonas aeruginosa exotoxin A. Pilin is a protein that is present on the surface of bacteria and other microorganisms, including P. aeruginosa. The key sequences are known to interact with asialoGM1 receptors on human epithelial cells, and allow bacteria and other microorganisms to adhere to epithelial cells and colonize. The present invention may be particularly useful for cystic fibrosis patients who are prone to infections with P. aeruginosa. Also, this invention could be a broad approach to vaccines against all gram negative bacteria, not just Pseudomonas aeruginosa. Pilin epitopes of other gram negative bacteria could be inserted into the Pseudomonas aeruginosa exotoxin A and used as a vaccine against that specific bacteria.

Dr. FitzGerald and his colleagues have demonstrated that the chimeric protein reacted with asialoGM1, a receptor on

epithelial cells and blocked adherence of P. aeruginosa on epithelial cells. When the chimeric protein was injected into rabbits, the rabbits produced antibodies that blocked bacterial adherence and neutralized the cell killing activity of native exotoxin A.

A Plasmid for Expression of a More Soluble Form of HIV Integrase Protein in E. coli

Robert Craigie (NIDDK)
DHHS Reference No. E–110–01/0
Licensing Contact: Sally Hu; 301/496–7056 ext. 265; e-mail: hus@od.nih.gov

The invention describes a plasmid that provides a convenient method for producing large quantities of integrase protein. This integrase protein is more soluble because amino acid residue Phe185 is changed to Lsy. This change does not affect the in vitro activity of the protein, but the improved solubility facilitates large-scale purification and handling. Since HIV integrase is a candidate target for antiviral drugs and an assay system or a source of HIV integrase is required to identify lead compounds, this invention could be very useful for an efficient means of producing integrase protein on a large scale. The integrase protein could be used in screening for integrase inhibitors that could be developed as anti-HIV drugs. This invention is available for licensing through a Biological Materials License, as no patent application exists.

Benzoylalkylindolepyridinium Compounds and Pharmaceutical Compositions Comprising Such Compounds

William G. Rice, Mingjun Huang, Robert W. Buckheit, Jr., David G, Covell, Grzegorz Czerwinski, Christopher Michejda, and Vadim Makarov (NCI)
DHHS Reference Nos. E–278–98/0 and E–278–98/1, filed Dec 18, 2000
Licensing Contact: Sally Hu; 301/496–7056 ext. 265; e-mail: hus@od.nih.gov

The present invention provides novel antiviral compounds active against HIV. These compounds, referred to as benzoylalkylindolepyridinium compounds (BAIPs) are effective against HIV isolates that have developed mutations rendering conventional drugs ineffective. BAIPs apparently do not require intracellular phosphorylation nor bind to the reverse transcriptase (RT) active site, which distinguishes their mechanism of action from the dideoxynucleoside (ddN) and acyclic nucleoside phosphonate (ANP) nucleoside analog drugs. ddN and ANP have proven clinically effective against limiting human immunodeficiency virus (HIV) infection, but resistance rapidly emerges due to mutations in and around the RT active site. The BAIPs also may be distinguished from non-nucleoside reverse transcriptase inhibitors (NNRTIs), in part because the BAIPs bind to a different site on the RT enzyme. The usage of NNRTIs is limited by the rapid emergence of resistant strains also. Moreover, unlike the NNRTIs, BAIPs of the present invention have been shown to be effective against HIV–1, HIV–2 and simian immunodeficiency virus (SIV) proliferation. Thus, BAIPs are broadly antiviral, non-nucleoside reverse transcriptase inhibitors (BANNRTIs).

This abstract modifies an abstract for this technology published in the **Federal Register** on Tuesday, February 13, 2001 (66 FR 10027).

Dated: May 17, 2001.

Jack Spiegel,

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

[FR Doc. 01–13345 Filed 5–25–01; 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, DHHS.

ACTION: Notice.

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Combined Inhibition of Phosphodiesterase-4 (PDE–4) and Phosphodiesterase-3 (PDF–3) as a Therapy for Th1 Mediated Autoimmune Diseases

Dr. Bibiana Bielekova et al. (NINDS)
DHHS Reference No. E–077–00/0, filed Dec 22 2000
Licensing Contact: Marlene Shinn; 301/496–7056 ext. 285; e-mail: shinnm@od.nih.gov

Hyperactive Th1-mediated immune responses are thought to be involved in the pathogenesis of many autoimmune diseases, including rheumatoid arthritis, diabetes, inflammatory bowel disease, vitiligo, and multiple sclerosis among others. Immune cells are known to produce primarily two classes of phosphodiesterases (PDE), the PDE4 and the PDE3 classes. Inhibitors of these PDEs have been shown to down-regulate the expression or production of Th1 cytokines and have either no effect or augment the production of Th2 cytokines, therefore making them good candidates for the treatment of Th1-mediated autoimmune diseases.

The NIH announces a new technology wherein PDE–4 and PDE–3 inhibitors are used in combination and a synergistic enhancement of therapeutic activity is achieved. This results in a more potent immunomodulatory effect on the immune cells and could lead to the administration of lower dose rate of the inhibitors. This new form of treatment will alleviate side effects through the use of a lower dose rate for each and will make for a more effective therapy.

Determination of AM-Binding Proteins and the Association of Adrenomedullin (AM) Therewith

F. Cuttitta et al. (NCI)
DHHS Reference No. E–256–99/1 filed, Sep 08 2000 (Note: This invention is related to E–206–95/3, filed Aug 18 1996, the disclosure of which is incorporated herein.)
Licensing Contact: Matthew Kiser; 301/496–7056 ext. 224; e-mail: kiserm@od.nih.gov

The present invention provides methods for the isolation, identification, and purification of adrenomedullin (AM)-binding proteins. Methods for utilizing the purified AM-binding proteins, or functional portions thereof, to diagnose, treat, and monitor AM-related diseases are described. A second aspect of this technology discloses the identification and isolation of a novel complex between AM and a specific AM-binding protein 1 (AMBP–1), designated factor H (fH). The identification of small molecule