the viral subtypes currently transmitted within the screened population and hence most likely to ''break-through'' routine screening measures (*i.e.*, peri-seroconversion window period donations). Molecular surveillance of incident HIV infections in blood donors not only characterizes genotypes of recently infected donors for purposes of blood safety, but also enables documentation of the rates of primary transmission of anti-viral drug resistant strains in the community, serving a public health role in identifying new HIV infections for anti-retroviral treatment. Both a prospective surveillance and a case-control design are proposed to enroll all eligible HIV seropositives detected at three blood centers in Brazil (São Paulo, Belo Horizante, and Recífe) plus a satellite center in Rio de Janeiro. A comparison of epidemiological risk profiles will be made between the seropositive donors and a group of randomly selected seronegative donors.

There are three study aims. Laboratory studies (LS–EIA testing and sequencing of pol region) on linked specimens from all enrolled HIV cases, will allow for estimation of HIV prevalence and incidence relative to genotype and putative route of infection. Data derived from molecular genotyping, including drug resistant genotypes, will be provided, along with counseling, to all enrolled HIV positive donors to facilitate their clinical care via referral to the Brazilian national HIV treatment system. Our findings will be compared to trends in prevalence, incidence and molecular variants from studies of the general population and high risk populations in Brazil, thus allowing for broad monitoring of the HIV epidemic in Brazil and assessment of the impact of donor selection criteria on these parameters. Finally, HIV cases and a group of controls, through responses to a questionnaire, will provide data on HIV risk behaviors among prospective blood donors. This HIV risk behavior data will be used as covariates in the molecular surveillance analyses described above, as well as aid in assessing whether modifications may be needed to Brazil's routine blood center operational donor screening questionnaire.

The study participants will return to their local blood center for the administration of an informed consent form, explaining the confidential nature of the research study as well as the risks and benefits to their participation. Once enrolled, they will be asked to complete the self-administered risk factor questionnaire. In addition, a small blood sample will be collected from each HIV seropositive participant to be used for the genotyping and drug resistance testing. The results of the drug resistance testing will be communicated back to the seropositive participants during an in-person counseling session at the blood center. Defining prevalence and incidence in blood donors and residual risk of HIV transmission by transfusions may lead to new regulations and blood safety initiatives in Brazil. The data can be used to project the yield, safety impact and cost effectiveness of implementing enhanced testing strategies such as combination antigen-antibody assays and/or NAT. Determination of HIV risk factors in donors (first time versus repeat donor status; volunteer versus replacement status; demographics and risk behaviors) will support policy discussions over strategies to recruit the safest possible donors in Brazil. The findings from this project will also complement similar monitoring of HIV prevalence, incidence, transfusion risk and molecular variants in the U.S. and other funded international REDS-II sites, thus allowing direct comparisons of these parameters on a global level.

Frequency of Response: Once. *Affected Public:* Individuals. *Type of Respondents*: Adult Blood Donors. The annual reporting burden is as follows: *Estimated Number of Respondents:* 2,000; *Estimated Number of Responses per Respondent*: 1; *Average Burden of Hours per Response*: 0.40 (including administration of the informed consent form and questionnaire completion instructions); and *Estimated Total Annual Burden Hours Requested:* 800. The annualized cost to respondents is estimated at: $5,200 (based on $6.50 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
2,000	1	0.40	800

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 the assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information 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 Dr. George Nemo, Project Officer, NHLBI, Two Rockledge Center, Room 9144, 6701 Rockledge Drive, MSC 7950, Bethesda, MD 20892–7950, or call 301–435–0065, orE-mail your request to *nemog@nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: May 20, 2008.

George Nemo,

Project Officer, NHLBI, National Institutes of Health.

[FR Doc. E8–11921 Filed 5–28–08; 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 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.

Telomerase Suppressor Compositions and Methods for Diagnosis and Treatment of Cancer

Description of Technology: Lung cancer is responsible for one-third of all cancer related deaths. Although tobacco smoking is a major cause of lung cancer, epidemiological studies have provided evidence for the involvement of genetic factors in the disease onset. For now there are no reliable markers for the early lung cancer diagnostics and no effective treatment except resection of the tumor on early stages. As a result, it is difficult to diagnose lung cancer without invasive methods and before significant progression of the disease has occurred.

NIH inventors have recently discovered that a gene called CCDC36 (LELA1) is frequently inactivated in patients with non-small cell lung cancer (NSCLC). In many instances of lung cancer, particularly early onset NSCLC, one copy of CCDC36 will be lost due to the chromosomal deletion while the other will be inactivated by promoter methylation. This results in reduction or loss of CCDC36 gene expression. In addition, several single nucleotide polymorphisms (SNPs) found in the gene appeared to be associated with the early onset NSCLC. CCDC36 gene replacement could be utilized as a potential therapeutic strategy.

Applications

Detection of SNPs associated with early onset NSCLC can be potentially used to diagnose predisposition.

Detection of chromosomal loss of CCDC36 and/or its methylation status in lung cancer can be used to diagnose NSCLC.

Treatment of NSCLC using CCDC36-based therapeutics.

Advantages

Early detection of NSCLC has the potential to improve prognosis of lung cancer patient.

Non-invasive nature of the test is beneficial to patient comfort.

Benefits

There is no current genetic test for early onset NSCLC, providing an excellent market opportunity.

Developing a diagnostic test for lung cancer will have significant social benefits, allowing the early detection and treatment of lung cancer patients.

Inventors: Tatiana Dracheva et al. (NCI).

Patent Status: PCT Application No. PCT/US2008/059800 filed 09 Apr 2008 (HHS Reference No. E–265–2007/0–PCT–01).

Licensing Status: Available for licensing.

Licensing Contact: David A. Lambertson, Ph.D.; 301–435–4632; *lambertsond@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute, Center for Cancer Research, Laboratory of Human Carcinogenesis is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize ''Unique Genetic Changes in CCDC36 Gene That Are Associated with Early Onset Lung Cancer.'' Please contact John D. Hewes, Ph.D., at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Muramyl Dipeptide as a Therapeutic Agent for Inflammation

Description of Technology: The nucleotide-binding oligomerization domain 2 (NOD2) protein plays a key role in innate immunity as a sensor of muramyl dipeptide (MDP), a breakdown product of bacterial peptidoglycan. Bacterial peptidoglycan promotes the innate immune response through the activation of Toll-like receptor 2 (TLR2), which ultimately provokes inflammation. Activation of NOD2 by MDP negatively regulates the activity of TLR2, and thus reduces inflammation.

The inventors have demonstrated that administration of MDP prevents the development of experimental colitis in mice. They have also determined that MDP reduces pro-inflammatory cytokine production from multiple Toll-like receptors, and that this reduction arises from the induction of IFN regulatory factor 4 (IRF4). The technology includes methods of treating or preventing inflammation associated with an autoimmune disorder, particularly inflammatory bowel disease, via administration of muramyl peptide; also included are methods of reducing symptoms characteristic of inflammation via administration of muramyl peptide.

Applications: This technology has potential as an anti-inflammatory therapy for autoimmune or other inflammation-associated diseases, particularly inflammatory bowel diseases such as Crohn's disease and ulcerative colitis.

Market: Approximately 1.8 million people suffer from inflammatory bowel disease in the major pharmaceutical markets. In the United States alone, there are approximately 300,000 to 500,000 people with inflammatory bowel disease, as estimated by the National Institute of Diabetes and Digestive and Kidney Diseases, NIH.

Development Status: In vivo data are available in an experimental colitis mouse model, and *in vitro* data supporting mechanism of action also are available.

Inventors: Warren Strober *et al.* (NIAID).

Relevant Publication: T. Watanabe et al. Muramyl dipeptide activation of nucleotide-binding oligomerization domain 2 protects mice from experimental colitis. J Clin Invest. 2008 Feb;118(2):545–559.

Patent Status: PCT Application No. PCT/US2007/086117 filed 30 Nov 2007 (HHS Reference No. E–110–2006/0–PCT–02).

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

Licensing Contact: Tara Kirby, Ph.D.; 301–435–4426; *tarak@mail.nih.gov.*

Collaborative Research Opportunity: The NIAID Laboratory of Host Defenses, Mucosal Immunity Section, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact either Rosemary Walsh or Charles Rainwater at 301–496–2644 for more information.

Treatment and Diagnosis of Cancer, Diabetes and Other Disorders Using Adrenomedullin Peptides and Antibodies

Description of Technology: Adrenomedullin (AM), a 52-amino acid regulatory peptide, is expressed in a wide range of tissues, and has a variety of biological roles. AM was initially identified as a vasodilator, and the effects of AM and its fragments in the cardiovascular system have been widely studied. AM also has important effects on renal function, cell growth, glucose

metabolism, and regulation of hormone secretion, and has antimicrobial activity.

This technology claims AM peptides and antibodies, which would be useful in the development of a therapeutic or for diagnostics use. Also claimed are methods of inhibiting tumor cell growth using AM peptides, in particular in a patient suffering from a lung tumor. Claims are also directed to methods of treating a subject with AM-associated conditions, including diabetes, pregnancy, neurological disease, inflammation, or bone development. Finally, methods are claimed for diagnosing or monitoring a disease where AM levels are altered.

Also available is a murine monoclonal antibody, MoAb-G6, which was raised against an AM peptide. This antibody neutralizes AM bioactivity, and reacts with the processed form of AM, but not the preprohormone. This antibody would be useful not only for research use, but also as part of a diagnostic assay for measurement or detection of AM.

Applications

Peptide- or antibody-based therapeutics for cancer, diabetes, inflammation or other AM-associated disease.

Diagnostic tools for the detection of AM-positive tumors or other AM-associated conditions.

Research use of AM peptides and antibodies.

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

Inventors: Frank Cuttitta et al. (NCI).

Related Publications

1. A Martínez et al. Regulation of insulin secretion and blood glucose metabolism by adrenomedullin. Endocrinology. 1996 Jun;137(6):2626–2632.

2. E Zudaire et al. The central role of adrenomedullin in host defense. J Leukoc Biol. 2006 Aug;80(2):237–244.

3. E Zudaire et al. Adrenomedullin is a cross-talk molecule that regulates tumor and mast cell function during human carcinogenesis. Am J Pathol. 2006 Jan;168(1):280–291.

Patent Status:

U.S. Patent Serial No. 6,320,022 issued 20 Nov 2001 (HHS Reference No. E–206–1995/3–US–04).

U.S. Patent Serial No. 7,101,548 issued 05 Sept 2006 (HHS Reference No. E–206–1995/3–US–10).

U.S. Patent Application No. 11/517,599 filed 05 Sept 2006 (HHS Reference No. E–206–1995/3–US–11).

Foreign counterparts in Australia, Canada, France, Germany, Great Britain, and Japan.

Related Technologies

HHS Reference No. E–256–1999/0—Determination of Adrenomedullin-Binding Proteins.

HHS Reference No. E–294–2002/0—A New Target for Angiogenesis and Anti-Angiogenesis Therapy.

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

Licensing Contact: Tara Kirby, Ph.D.; 301–435–4426; *tarak@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute Angiogenesis Core Facility is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Use of Adrenomedullin Peptides and Antibodies in the Treatment and Diagnosis of Cancer, Diabetes and other Disorders. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: May 21, 2008.

Steven M. Ferguson,

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

[FR Doc. E8–11919 Filed 5–28–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, June 26, 2008, 1 p.m. to June 26, 2008, 3 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on May 16, 2008, 73 FR 28489–28490.

The meeting will be held June 24, 2008, 2 p.m. to 3 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: May 20, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–11785 Filed 5–28–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, June 23, 2008, 8 a.m. to June 24, 2008, 5 p.m., Sir Francis Drake Hotel, 450 Powell Street, San Francisco, CA 94102 which was published in the **Federal Register** on May 16, 2008, 73 FR 28489–28490.

The meeting will be held one day only June 23, 2008, from 8 a.m. to 7 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: May 20, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–11787 Filed 5–28–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, June 17, 2008, 1 p.m. to June 17, 2008, 3 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on May 15, 2008, 73 FR 28121–28122.

The meeting will be held June 20, 2008, 11 a.m. to 2 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: May 20, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–11788 Filed 5–28–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Cancellation of Meeting

Notice is hereby given of the cancellation of the Neurotechnology Study Section, June 3, 2008, 8 a.m. to June 4, 2008, 5 p.m., Grand Hyatt, 345 Stockton Street, San Francisco, CA