Dated: February 28, 2008.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E8–4269 Filed 3–4–08; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Reimbursement of Travel and Subsistence Expenses Toward Living Organ Donation Eligibility Guidelines

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Request for Comments on Proposed Changes to the Reimbursement of Travel and Subsistence Expenses Program Eligibility Criteria.

SUMMARY: The Health Resources and Services Administration (HRSA) published the final eligibility guidelines for the Reimbursement of Travel and Subsistence Expense Program in the **Federal Register** on October 5, 2007 (72 FR 57049). The purpose of this notice was to inform the public of the eligibility requirements for participation in the Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation Program. HRSA is requesting public comments concerning recommended change to a specific section of the reimbursement program eligibility guidelines.

DATES: Written comments must be submitted to the office in the address section below by mail or e-mail on or before April 4, 2008.

ADDRESSES: Please send all written comments to James F. Burdick, M.D., Director, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, Room 12C–06, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443–7577; fax (301) 594–6095; or e-mail: *jburdick@hrsa.gov*.

FOR FURTHER INFORMATION CONTACT: James F. Burdick, M.D., Director, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 12C–06, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443–7577; fax (301) 594–6095; or e-mail: *jburdick@hrsa.gov*.

SUPPLEMENTARY INFORMATION: In its final program eligibility guidelines, HRSA explained that ''[t]he Program will pay for a total of up to five trips; three for the donor and two for accompanying persons. The accompanying persons need not be the same each trip.'' (72 FR 57052). HRSA proposes amending this paragraph to read: ''[t]he Program will pay for a total of up to five trips; three for the donor and two for accompanying persons. However, in cases in which the transplant center requests the donor to return to the transplant center for additional visits as a result of donor complications or other health related issues, NLDAC may provide reimbursement for the additional visit(s) for the donor and an accompanying person. The accompanying persons need not be the same in each trip.'' The purpose of this proposed change is to accommodate individuals who experience donor complications or other health related issues relating to donation.

HRSA is requesting comments on this specific section.

Dated: February 26, 2008.

Elizabeth M. Duke,

Administrator.

[FR Doc. E8–4185 Filed 3–4–08; 8:45 am]

BILLING CODE 4165–15–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.

PSM Peptides as Vaccine Targets Against Methicillin-Resistant

Staphylococcus aureus

Description of Technology: Available for licensing and commercial development are compositions and methods for the treatment and inhibition of Methicillin-resistant *Staphylococcus aureus* (MRSA), a dangerous human pathogen. The invention concerns immunogenic peptides that can be used to induce protective immunity against MRSA, including phenol-soluble modulin (PSM) peptides.

In addition to the MRSA infections that occur in immunocompromised patients in hospitals, new MRSA strains have recently emerged that can cause severe infections (such as necrotizing fasciitis) or death in otherwise healthy adults. These strains are increasingly involved in community-associated (CA)–MRSA infections, and can be contracted outside of the health care settings. The incidence of CA–MRSA infections is increasing and the majority of infections in patients reporting to emergency departments in the U.S. is now due to CA–MRSA.

The invention describes a class of secreted staphylococcal peptides with an extraordinary ability to recruit, activate, and subsequently lyse human neutrophils, thus eliminating the main cellular defense against *S. aureus* infection. The peptides are encoded by the PSM gene cluster and include PSMα1, PSMα2, PSMα3, and PSMα4, all of which activate and subsequently lyse neutrophils. These peptides are produced at especially high levels in CA–MRSA and to a large extent determine their aggressive behavior and ability to cause disease in animal models of infection. Thus, the peptides represent a set of virulence factors of *S. aureus* that account for the enhanced virulence of CA–MRSA. The identification of these peptides enables the production of vaccines and other preventative and/or therapeutic agents for use in subjects infected with MRSA.

Applications: Development of new classes of antibiotics and vaccines against Methicillin-resistant *Staphylococcus aureus* infections.

Inventors: Michael Otto and Rong Wang (NIAID).

Publication: R Wang et al. Identification of novel cytolytic peptides as key virulence determinants for community-associated MRSA. Nat Med. 2007. Dec;13(12):1510–1514.

Patent Status: U.S. Provisional Application No. 60/933,573 filed 06 Jun 2007 (HHS Reference No. E–239–2007/0–US–01); U.S. Provisional Application

No. 60/983,141 filed 26 Oct 2007 (HHS Reference No. E–239–2007/1–US–01).

Development Status: Early stage.

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

Licensing Contact: Cristina Thalhammer-Reyero, PhD., M.B.A.; 301–435–4507; *thalhamc@mail.nih.gov*.

Collaborative Research Opportunity: The NIAID Laboratory of Human Bacterial Pathogenesis is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact William Ronnenberg at 301–451–3522 or *wronnenberg@mail.nih.gov* for more information.

Active MRI Compatible and Visible iMRI Catheter

Description of Technology: MRI is a promising imaging modality that provides superior soft tissue contrast and multi planar real-time imaging without harmful ionizing radiation for therapeutic procedures. Interventional magnetic resonance imaging (iMRI) has gained important popularity in many fields such as interventional cardiology and radiology, owing to the development of minimally invasive techniques and visible catheters under MRI for conducting MRI-guided procedures and therapies. This invention relates to a novel MRI compatible and active visible catheter for conducting interventional and intraoperative procedures under the guidance of MRI. The catheter features a non conductive transmission line and the use of ultrasonic transducers that transform RF signals to ultrasonic signals for transmitting RF signal to the MRI scanner. The unique design of this catheter overcomes the concern of patient/sample heating (due to the coupling between RF transmission energy and long conductors within catheter) associated with the design of conventional active MRI catheters.

Inventor: Ozgur Kocaturk (NHLBI).

Patent Status: U.S. Provisional Application No. 60/716,503 filed 14 Sep 2005 (HHS Reference No. E–298–2005/0–US–01); PCT Application No. PCT/US2006/035636 filed 13 Sep 2006, which published as WO 2007/033240 on 22 Mar 2007 (HHS Reference No. E–298–2005/0–PCT–02).

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

Licensing Contact: Michael Shmilovich, Esq.; 301/435–5019; *shmilovm@mail.nih.gov*.

Collaborative Research Opportunity: The National Heart, Lung, and Blood Institute, Cardiac Catheterization Lab is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the alternative Active MRI compatible and visible catheters using ultrasonic technology. Please contact Peg Koelble at *koelblep@nhlbi.nih.gov* for more information.

Immunoglobulins With Potent and Broad Antiviral (HIV) Activity Based on scFv Joined by Flexible Linker to Fc

Description of Technology: This invention describes methods of inhibiting viral infection (e.g., HIV–1 infection). The method comprises administering a fusion protein comprising a small size, single chain Fv (scFv) antibody binding domain joined to an Fc region by a long flexible linker. In particular, scFv m6 or m9, the single chain variable fragments that were previously identified from a phage display library for binding to $gp140_{89.6}$, $gp120_{JRFL}$, $gp140_{IIIB}$, and their complex with two-domain soluble CD4 is joined to Fc by a long flexible linker to provide a new agent for the inhibition of HIV infection or immunotherapy of HIV-infected individuals. The Fc region provides stability, long half-life, and biological effector functions. The scFv-Fc fragment provides antigen recognition and neutralizing activity. The small size of the scFv-Fc fusion molecule provides easy access to conserved viral epitopes exposed before or during viral entry. In addition, these fusion molecules exhibit neutralization activity that is higher than that of whole IgGs. Thus, this invention may offer a novel approach to treat and prevent HIV–1 infection and/or AIDS.

Inventors: Dimiter Dimitrov (NCI) and Mei-Yun Zhang (NCI/SAIC).

Patent Status: U.S. Patent Application No. 10/573,962 filed 29 Mar 2006, claiming priority to 29 Sep 2003 (HHS Reference No. E–316–2003/0–US–03).

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

Licensing Contact: Sally Hu; 301/435–5606; *hus@mail.nih.gov*.

Modulators of Nuclear Hormone Receptor Activity: Novel Compounds, Diverse Applications for Infectious Diseases, Including Anthrax (*B. anthracis*)

Description of Technology: Nuclear hormones such as glucocorticoids dampen inflammatory responses, and thus provide protection to mammals against inflammatory disease and septic shock. The Anthrax lethal factor represses nuclear hormone receptor activity, and thus may contribute to the infectious agent causing even more damage to the host. This observation can be exploited to find new means of studying and interfering with the normal function of nuclear hormone receptors. Scientists at NIH have shown that under the appropriate conditions, these molecules can be used to modulate the activity of various nuclear hormone receptors. Identifying useful agents that modify these important receptors can provide relief in several human disorders such as inflammation, autoimmune disorders, arthritis, malignancies, shock and hypertension.

Applications: This invention provides novel agents that can interfere with the action of nuclear hormone receptors. It is well known that malfunction or overdrive of these receptors can lead to a number of diseases such as enhanced inflammation; worse sequelae of infection including shock; diabetes; hypertension and steroid resistance. Hence a means of controlling or fine-tuning the activity of these receptors can be of great benefit. Current means of affecting steroid receptor activity are accompanied by undesirable side-effects. Since the conditions for which these treatments are sought tend to be chronic, there is a critical need for safer drugs that will have manageable side-effects.

Advantages: The observation that the lethal factor from Anthrax has a striking effect on the activity of nuclear hormone receptors opens up new routes to controlling their activity. The means of action of this repressor is sufficiently different from known modulators of hormone receptors (i.e., the classical antagonists). For instance, the repression of receptor activity is non-competitive, and does not affect hormone binding or DNA binding. Also, the efficacy of nuclear hormone receptor repression by Anthrax lethal factor is sufficiently high that the pharmacological effect of this molecule is seen at vanishingly small concentrations. Taken together, these attributes may satisfy some of the golden rules of drug development such as the uniqueness or novelty of the agent's structure, a low threshold for activity, high level of sophistication and knowledge in the field of enquiry, and the leeway to further refine the molecule by rational means.

Development Status: In vitro studies have been completed, and a limited number of animal studies have been carried out.

Inventors: Esther M. Sternberg (NIMH), Jeanette Webster (NIMH), Leonardo H. Tonelli (NIMH), Stephen H. Leppla (NIAID), Mahtab Moayeri (NIAID).

Patent Status: U.S. Patent Application No. 10/530,254 filed 04 Apr 2005,

claiming priority to 04 Oct 2002 (HHS Reference No. E–247–2002/1–US–02).

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

Licensing Contact: Peter Soukas; 301/435–4646; *soukasp@mail.nih.gov*.

Dated: February 27, 2008.

Bonny Harbinger,

Deputy Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E8–4187 Filed 3–4–08; 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.

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Novel Adjuvant Therapy Using TIMP–2 Variants

Description of Technology: Angiogenesis inhibitors are drugs that are being used in cancer therapy to block the development of new blood vessels which could potentially cut off a tumor's supply of oxygen and nutrients. This in turn might stop the tumor from growing and spreading to other parts of the body.

Human protein tissue inhibitor of metalloproteinases-2 (TIMP–2) has been shown to inhibit angiogenesis *in vivo* independent of metalloproteinase inhibition. The inventors have demonstrated that TIMP–2, as well as TIMP–2 variants lacking metalloproteinase inhibitor activity can revert aggressive tumor cell phenotype to a more differentiated state. In addition, TIMP–2 and the TIMP–2 variants also sensitize tumor cells to the induction of apoptosis by cytotoxic drugs (doxorubicin), thereby enhancing their effectiveness. Novel methods of cancer therapy are disclosed using TIMP–2 or TIMP–2 variants that combine the known anti-angiogenic activity of TIMP–2, with direct tumor-differentiating and chemo-sensitizing activity of TIMP–2.

Applications:

TIMP–2 or TIMP–2 variants can be administered for the inhibition of tumor cell growth and promotion of tumor cell differentiation.

TIMP–2 or TIMP–2 variants can be administered to enhance the cytotoxic activity of a chemotherapeutic agent.

Adjuvant therapy has application in the treatment of wide variety of carcinomas or melanomas.

Advantages:

A novel cancer therapy that combines the known anti-angiogenic activity of TIMP–2, with a novel direct tumor-differentiating and chemo-sensitizing activity of TIMP–2.

Enhances cytotoxicity of conventional chemotherapeutic agents when combined with TIMP–2 or TIMP–2 variants.

Development Status: In vivo and *in vitro* experiments have been conducted. The technology continues to be developed.

Market:

600,000 deaths from cancer related diseases estimated in 2007.

The technology platform involving novel anti-angiogenic cancer therapy technology has a potential market of more than 2 billion U.S. dollars.

Inventors: William G. Stetler-Stevenson et al. (NCI).

Publication: DW Seo, H Li, L Guedez, PT Wingfield, T Diaz, R Salloum, BY Wei, WG Stetler-Stevenson. TIMP–2 mediated inhibition of angiogenesis: an MMP-independent mechanism. Cell. 2003 Jul 25;114(2):171–180. [*PubMed abs*]

Patent Status: U.S. Provisional Application No. 60/953,352 filed 01 Aug 2007 (HHS Reference No. E–297–2007/0–US–01).

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

Licensing Contact: Surekha Vathyam; 301–435–4076; *vathyams@mail.nih.gov*.

Collaborative Research Opportunity: The NCI Laboratory of Extracellular Matrix Pathology, Cell and Cancer Biology Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize novel cancer therapy methods using TIMP–2 variants. Please contact John D. Hewes, Ph.D., at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Mucin Genes as a Diagnosis Marker for Pulmonary Fibrosis

Description of Technology: Familial pulmonary fibrosis (FPF) is a rare type of interstitial lung disease for which there is currently no cure. FPF is part of a group of interstitial lung diseases called idiopathic interstitial pneumonias (IIP) that lead to hypoxic respiratory insufficiency. The current invention has identified genes that are associated with FPF, and a possible means of early detection and treatment. The invention discloses an association between FPF and mutations in the genes encoding the MUC2 and MUC5AC mucins that predispose a subject to IIP. The occurrence of single nucleotide polymorphisms (SNPs) in these mutant genes further enable a significant diagnostic association between these polymorphisms and both familial and sporadic forms of pulmonary fibrosis. This invention may also have diagnostic value for other IIPs including idiopathic pulmonary fibrosis (IPF); a disease that presents late in life and is lethal within 4–5 years of diagnosis.

This technology presents opportunities for early detection of subjects at high risk for the development of pulmonary fibrosis, and possibly other similar diseases such as asthma, chronic obstructive pulmonary disease (COPD) and obliterative bronchitis, which also involve fibrosis of the airways. It is also conceivable that mucin, and synthetic molecules that mimic it, may be used as therapeutic agents for the prevention and treatment of pulmonary fibrosis.

Applications: Diagnosis of diseases involving pulmonary fibrosis.

Inventors: David A. Schwartz (NIEHS), Lauranell H. Burch (NIEHS), *et al.*

Publication: MP Steele, MC Speer, JE Loyd, KK Brown, A Herron, SH Slifer, LH Burch, MM Wahidi, JA Phillips III, TA Sporn, HP McAdams, MI Schwarz, DA Schwartz. Clinical and Pathologic Features of Familial Interstitial Pneumonia. Am J Respir Crit Care Med. 2005 Nov 1;172(9): 1146–1152.

Patent Status: U.S. Provisional Application No. 60/992,079 filed 03 Dec 2007 (HHS Reference No. E–016–2007/0–US–01).

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