

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Advisory Committee on Interdisciplinary, Community-Based Linkages; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

*Name:* Advisory Committee on Interdisciplinary, Community-Based Linkages (ACICBL).

*Dates and Times:* August 13, 2007, 1 p.m.-5 p.m., EST.

*Place:* (Audio Conference Call).

The ACICBL will meet on Monday, August 13, 2007 from 1 p.m. to 5 p.m. (EST). The public can join the meeting via audio conference by dialing 1-888-697-8510 and providing the following information:

*Leader's Name:* Mr. Lou Coccodrilli.

*Passcode:* 43495.

*Status:* The meeting will be open to the public; teleconference access limited only by availability of telephone ports.

*Purpose:* The Committee will continue to focus on issues related to Health Information Technology/Electronic Medical Records (HIT/EMR) and its potential impact on Title VII Interdisciplinary, Community-Based Training Grant Programs identified under sections 751-756, Part D of the Public Health Service Act. The Committee may invite speakers to highlight various topics related to HIT/EMR including, but not limited to benefits and barriers; consumer privacy and confidentiality; implications on underserved and unserved populations, rural, geriatric and other populations; implementation and use of EMRs across various settings, i.e., hospitals, inpatient settings and ambulatory care sites (Health Centers, Rural Health Clinics); academic settings, i.e., interdisciplinary and community-based education and training of health professionals; health literacy and patient education; as well as the future of HIT/EMR as an interoperable system to enhance health care delivery. The meeting will allow committee members the opportunity to identify and discuss current efforts involving HIT/EMR and formulate appropriate recommendations for the Secretary and the Congress regarding the use of advanced technology to enhance interdisciplinary and community-based training of health professions students and practicing health professionals.

*Agenda:* The agenda includes an overview of the Committee's general business activities, presentations by experts on HIT/EMR related topics, and discussion sessions for the development of recommendations to be addressed in the Seventh Annual ACICBL Report.

Agenda items are subject to change as dictated by the priorities of the Committee.

#### FOR FURTHER INFORMATION CONTACT:

Anyone requesting information regarding the Committee should contact

Louis D. Coccodrilli, Designated Federal Official for the ACICBL, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Rm 9-05, 5600 Fishers Lane, Rockville, Maryland 20857; (301) 443-6950 or [lcoccodrilli@hrsa.gov](mailto:lcoccodrilli@hrsa.gov). Vanessa Saldanha, Public Health Fellow can also be contacted for inquiries at (301) 443-6529 or [vsaldanha@hrsa.gov](mailto:vsaldanha@hrsa.gov).

Dated: July 24, 2007.

**Alexandra Huttinger,**

*Acting Director, Division of Policy Review and Coordination.*

[FR Doc. E7-14528 Filed 7-26-07; 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.

#### **Monoclonal Antibodies that Neutralize B. anthracis Protective Antigen (PA), Lethal Factor (LF) and Edema Factor (EF)**

*Description of Technology:* Anthrax, whether resulting from natural or bioterrorist-associated exposure, is a constant threat to human health. The lethality of anthrax is primarily the result of the effects of anthrax toxin, which has 3 components: a receptor-binding protein known as "protective antigen" (PA) and 2 catalytic proteins known as "lethal factor" (LF) and "edema factor" (EF). Although

production of an efficient anthrax vaccine is an ultimate goal, the benefits of vaccination can be expected only if a large proportion of the population at risk is immunized. The low incidence of anthrax suggests that large-scale vaccination may not be the most efficient means of controlling this disease. In contrast, passive administration of neutralizing human or chimpanzee monoclonal antibody to a subject at risk for anthrax or exposed to anthrax could provide immediate efficacy for emergency prophylaxis against or treatment of anthrax.

Four monoclonal antibodies (mAbs) against PA, three mAbs against LF and four mAbs specific for EF of anthrax were isolated from a phage display library generated from immunized chimpanzees. Two mAbs recognizing PA (W1 and W2), two anti-LF mAbs efficiently neutralized the cytotoxicity of lethal toxin in a macrophage lysis assay. One anti-EF mAb efficiently neutralized edema toxin in cell culture. All five neutralizing mAbs protected animals from anthrax toxin challenge.

*Application:* Prophylactics or therapeutics against *B. anthracis*.

*Developmental Status:* Preclinical studies have been performed.

*Inventors:* Zhaochun Chen, Robert Purcell, Suzanne Emerson, Stephen Leppla, Mahtab Moyeri (NIAID).

*Publication:* Z Chen et al. Efficient neutralization of anthrax toxin by chimpanzee monoclonal antibodies against protective antigen. *J Infect Dis.* 2006 Mar 1;193(5):625-633. Epub 2006 Feb 2.

*Patent Status:* U.S. Provisional Application No. 60/903,022 filed 23 Feb 2007 (HHS Reference No. E-123-2007/0-US-01); U.S. Patent Application filed 22 Jun 2007 (HHS Reference No. E-146-2004/0-US-03).

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

*Licensing Contact:* Peter A. Soukas, J.D.; 301/435-4646; [soukasp@mail.nih.gov](mailto:soukasp@mail.nih.gov).

*Collaborative Research Opportunity:* The National Institute of Allergy and Infectious Diseases, Laboratory of Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Chimpanzee/human neutralizing monoclonal antibodies against anthrax toxins. Please contact Dr. Robert Purcell at 301-496-5090 for more information.

#### **Use of Amyloid Proteins as Vaccine Scaffolds**

*Description of Technology:* Amyloid proteins are composed of peptides

whose chemical properties are such that they spontaneously aggregate in vitro or in vivo, assuming parallel or antiparallel beta sheet configurations. Amyloid proteins can arise from peptides which, though differing in primary amino acid sequences, assume the same tertiary and quaternary structures. The amyloid structure presents a regular array of accessible N-termini of the peptide molecules.

Claimed in this application are compositions and methods for use of amyloid proteins as vaccine scaffolds, on which peptide determinants from microorganisms or tumors may be presented to more efficiently generate and produce a sustained neutralizing antibody response to prevent infectious diseases or treat tumors. The inventors have arrayed peptides to be optimally immunogenic on the amyloid protein scaffold by presenting antigen using three different approaches. First, the N-terminal ends of the amyloid forming peptides can be directly modified with the peptide antigen of interest; second, the N-termini of the amyloid forming peptides are modified with a linker to which the peptide antigens of interest are linked; and third, the scaffold amyloid may be modified to create a chimeric molecule.

Aside from stability and enhanced immunogenicity, the major advantages of this approach are the synthetic nature of the vaccine and its low cost. Thus, concerns regarding contamination of vaccines produced from cellular substrates, as are currently employed for some vaccines, are eliminated; the robust stability allows the amyloid based vaccine to be stored at room temperature for prolonged periods of time; and the inexpensive synthetic amino acid starting materials, and their rapid spontaneous aggregation in vitro should provide substantial cost savings over the resource and labor-intensive current vaccine production platforms.

**Application:** Immunization to prevent infectious diseases or treat chronic conditions or cancer.

**Developmental Status:** Vaccine candidates have been synthesized and preclinical studies have been performed.

**Inventors:** Amy Rosenberg (CDER/FDA), James E. Keller (CBER/FDA), Robert Tycko (NIDDK).

**Patent Status:** U.S. Provisional Application No. 60/922,131 filed 06 Apr 2007 (HHS Reference No. E-106-2007/0-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](mailto:soukasp@mail.nih.gov).

**Collaborative Research Opportunity:** The FDA, Division of Therapeutic Proteins (CDER) and Office of Vaccines, Division of Bacterial Products (CBER) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize amyloid based vaccines for prevention of infectious disease or treatment of malignant states. Please contact Amy Rosenberg at [amy.rosenberg@fda.hhs.gov](mailto:amy.rosenberg@fda.hhs.gov) or (301) 827-1794 for more information.

Dated: July 19, 2007.

**Steven M. Ferguson,**

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

[FR Doc. E7-14500 Filed 7-26-07; 8:45 am]

**BILLING CODE 4140-01-P**

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#### Transgenic Mouse Model for Lupus and Other Autoimmune Diseases

**Description of Technology:** The inventors have developed a series of transgenic mice that overexpress Toll-Like Receptor 7 (TLR7) at different levels. Overexpression of TLR7 in these mice results in a lupus-like syndrome, the intensity of which correlates with

the level of overexpression. As the pathology in these mice results from the overexpression of a single gene, it represents a superior model for lupus and other autoimmune diseases compared to other existing mouse models that dysregulate multiple genes to achieve the same pathologic syndrome.

Two strains are currently available. The TLR7.Tg1 strain overexpresses TLR7 at approximately 16 times the wild-type level. The TLR7.Tg6 strain overexpresses TLR7 at approximately 4 times the level of a wild-type mouse; additionally, the transgene for this strain is located on the Y chromosome, which would be advantageous for cross-breeding to other mouse lines.

**Inventors:** Jonathan Deane *et al.* (NIAID).

**Related Publication:** P. Pisitkun *et al.* Autoreactive B cell responses to RNA-related antigens due to TLR7 gene duplication. *Science* 2006 Jun 16;312(5780):1669-1672.

**Patent Status:** HHS Reference No. E-128-2007/0—Research Tool.

**Licensing Status:** This technology is available for nonexclusive licensing.

**Licensing Contact:** Tara L. Kirby, Ph.D.; 301/435-4426; [tarak@mail.nih.gov](mailto:tarak@mail.nih.gov).

#### Dysphagia Rehabilitation (Swallowing Recovery): Vibro-Tactile Stimulation Device and Method for Motor Control Recovery

**Description of Technology:** Available for licensing and/or commercial development under a scientific collaboration, are device and method patents for volitional swallowing with a substitute sensory system. The inventions are potentially applicable to a wide variety of indications, including recovery post-stroke and post extubation for example, after coronary bypass surgery. The device is being tested in dysphagic patients in two, ongoing clinical trials at the National Institutes of Health. A collaborator or licensee is needed to support further clinical trials, validation studies, and final package development.

**Device:** For the device patent, upon activation a vibrator moves and vibrates the larynx. Patients can initiate sensory stimulation immediately prior to the patient's own initiation of a swallow. Specifically, the device allows the patient to coordinate muscular movement with a button press to permit volitional swallowing. The device can also include a movement sensor for monitoring pressure on the patient's larynx and a swallowing detector. The swallowing detector includes a piezoelectric stretch receptor and a