

individuals using influenza whole genome phage display at "Immunobiology and Pathogenesis of Influenza Infection", Atlanta: June 1–3, 2008. (poster presentation).

**Patent Status:** International Patent Application PCT/US2008/067001 filed 13 Jun 2008 (HHS Reference No. E–236–2007/3–PCT–01).

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

**Licensing Contact:** Kevin W. Chang, Ph.D.; 301–435–5018; [changke@mail.nih.gov](mailto:changke@mail.nih.gov).

**Collaborative Research Opportunity:** The FDA, Center for Biologics Evaluation and Research (CBER), Division of Viral Products, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize these peptides as vaccine candidates or diagnostics. Please contact Alice Welch at [alice.welch@fda.hhs.gov](mailto:alice.welch@fda.hhs.gov) or 301–827–0359 for more information.

#### **A Rapid Ultrasensitive Assay for Detecting Prions Based on the Seeded Polymerization of Recombinant Normal Prion Protein (rPrP-sen)**

**Description of Technology:** Prion diseases are neurodegenerative diseases of great public concern because humans may be infected from hooved animals used as food, food products such as milk, or blood products. Currently available tests for disease-causing prions are either incapable of detecting low concentrations of prions and must be used post-mortem or are incapable of detecting low concentrations of prions economically or accurately. This technology enables rapid and economical detection of sub-lethal concentrations of prions by using recombinant, normal, prion protein (rPrP-sen) as a marker or indicator of infectious prions in a sample. Specifically, prions (contained in a sample) seed the polymerization of rPrP-sen, and polymerized rPrP-sen is detected as an amplified indicator of prions in the sample. This assay differs from the protein-misfolding cyclic amplification assay (PMCA) because it enables the effective use of rPrP-sen and does not require multiple amplification cycles unless a higher degree of sensitivity is required. It is anticipated that this technology can be combined with additional prion-detection technologies to further improve the sensitivity of the assay. In its current embodiment, this assay has been used to detect prions in brain tissue or cerebral spinal fluid (CSF) from humans (variant CJD), sheep (scrapie), and hamsters (scrapie).

**Advantages:**

- Uses a consistent, concentrated source of normal prion protein (rPrP-sen)
  - Prions are detectable to low levels after a single amplification round
  - May be combined with complimentary detection technologies to improve sensitivity
  - Demonstrated to be effective at detecting prions from different species
  - May be applicable to blood products
  - Economical
- Applications:**
- A test for live animals or food products
  - A human diagnostic for early detection of prion diseases
  - Monitor for effectiveness of treatments or disease progression

**Inventors:** Byron W. Caughey, Ryuichiro Atarashi, Roger A. Moore, and Suzette A. Priola (NIAID).

#### **Related Publications:**

1. R Atarashi et al. Simplified ultrasensitive prion detection by recombinant PrP conversion with shaking. *Nat Methods* 2008 Mar;5(3):211–212.
2. R Atarashi et al. Ultrasensitive detection of scrapie prion protein using seeded conversion of recombinant prion protein. *Nat Methods* 2007 Aug;4(8):645–650.

#### **Patent Status:**

- PCT Application No. PCT/US2008/070656 filed 21 Jul 2008 (HHS Reference No. E–109–2007/1–PCT–01).
- U.S. Application No. 12/177,012 filed 21 Jul 2008 (HHS Reference No. E–109–2007/1–US–02).

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

**Licensing Contact:** RC Tang, JD, LLM; 301–435–5031; [tangrc@mail.nih.gov](mailto:tangrc@mail.nih.gov).

**Collaborative Research Opportunity:** The NIAID Laboratory of Persistent Viral Diseases, TSE/Prion Biochemistry Section, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Rosemary Walsh at 301–451–3528 or [rcwalsh@niaid.nih.gov](mailto:rcwalsh@niaid.nih.gov).

Dated: September 18, 2008.

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

[FR Doc. E8–22610 Filed 9–25–08; 8:45 am]

**BILLING CODE 4140–01–P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **National Institute of Diabetes and Digestive and Kidney Diseases; Amended Notice of Meeting**

Notice is hereby given of a change in the meeting of the National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, October 17, 2008, 2:30 p.m. to 3:30 p.m., National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 which was published in the **Federal Register** on September 11, 2008, 73 FR 0177.

This meeting will be held October 22, 2008 instead of October 17, 2008. The meeting is closed to the public.

Dated: September 18, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E8–22604 Filed 9–25–08; 8:45 am]

**BILLING CODE 4140–01–P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **National Institute of Diabetes and Digestive and Kidney Diseases; 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 Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Molecular Therapy Core Centers.

**Date:** October 21, 2008.

**Time:** 8 a.m. to 5 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

**Contact Person:** Michele L. Barnard, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 753, 6707 Democracy Boulevard,