

301-827-5988, e-mail:  
lou.gallagher@fda.hhs.gov.

**Registration:** Mail, fax, or e-mail your registration information (including name, title, firm name, address, telephone and fax numbers) to Lou Gallagher (see *Contact Person*) by November 10, 2011. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Lou Gallagher (see *Contact Person*) at least 7 days in advance.

#### **SUPPLEMENTARY INFORMATION:**

Quantitative risk assessments (QRAs) are an important tool for evaluating the risks associated with new emerging infectious diseases (EIDs) that are relevant to blood and blood products and the benefits of mitigation options. QRAs make it possible for decisionmakers to develop policy for blood and blood product safety and availability using sound science and the best data and information available.

Rapid data collection, information sharing, and analyses estimating the magnitude and probability of risk can be expedited by proactively building and maintaining critical relationships both within the Center for Biologics Evaluation and Research (CBER) and with external stakeholders. In this public workshop, CBER is seeking access to accurate, reliable data on factors such as disease prevalence, incubation periods, behavioral risks associated with disease transmission, potential donor exposure risks, and susceptibility to EIDs, product handling, usage, and other factors.

Lack of data and information is a major challenge FDA faces when there is a new EID. The public workshop will: (1) Provide a forum for discussion of data used in conducting quantitative risk assessments for EIDs, (2) address approaches to facilitate the timely access to data required to evaluate public health measures designed to reduce the potential risk associated with EIDs that are relevant to blood and blood products, and (3) provide a forum for discussion of the development of new data sources and enhanced access to already existing data sources.

**Transcripts:** Please be advised that as soon as possible after a transcript of the public workshop is available, it will be accessible on the Internet at: <http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/>

[WorkshopsMeetingsConferences/](#)

[TranscriptsMinutes/default.htm](#).

Transcripts of the public workshop may also be requested in writing from the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857.

Dated: October 6, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-26295 Filed 10-11-11; 8:45 am]

**BILLING CODE 4160-01-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.

#### **Human Phospho-Serine134 Glucocorticoid Receptor Polyclonal Antibody: Useful for the Characterization of Glucocorticoid Signaling Processes, e.g., in Cancer and Inflammation**

**Description of Technology:** The glucocorticoid receptor (GR) functions as a hormone-dependent transcription factor that is involved in the maintenance of basal and stress-related homeostasis. Serine 134 is a newly discovered phosphorylation target on the human glucocorticoid receptor that becomes phosphorylated during stress-activating conditions such as ultraviolet irradiation, nutrient starvation, and oxidative stress. The inventors have

developed a rabbit polyclonal antibody that specifically recognizes the Ser 134 phosphorylated form of the human glucocorticoid receptor. This antibody may be particularly useful for a variety of basic research applications, such as the characterization and study of glucocorticoid signaling in cancer, inflammation, and other diseases.

The antibody is available as crude antisera and has been epitope purified; it has cross reactivity with human, rat, and mouse tissues.

**Potential Commercial Applications:** Western analysis, immunoprecipitation, and immunofluorescence studies.

**Inventors:** Amy Beckley and John Cidlowski (NIEHS).

**Related Publication:** Molecular and Cellular Biology, *In Press*.

**Intellectual Property:** HHS Reference No. E-182-2011/0—Research Tool.

Patent protection is not being pursued for this technology.

**Licensing Status:** This technology is available as a research tool under a Biological Materials License.

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

**Collaborative Research Opportunity:** The NIEHS, Molecular Endocrine Group, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Human Phospho-Serine134 Glucocorticoid Receptor Polyclonal Antibody. Please contact Elizabeth M. Denholm at [denholme@niehs.nih.gov](mailto:denholme@niehs.nih.gov) for more information.

#### **Infectious Hepatitis E Virus Genotype 3 Recombinants—Prospective Vaccine Candidates and Vector System**

**Description of Technology:** Infection by Hepatitis E virus (HEV) is a relevant health issue in a number of developing countries and it is also an emerging food-borne disease of industrialized countries. Genotype 1 and 2 infections are found exclusively in humans while genotype 3 and 4 viruses have been found not only in humans, but also swine, deer, mongoose, cattle, and rabbits. In particular, genotype 3 and 4 viruses are ubiquitously found in swine and undercooked pork is thought to be one of the sources of infection for cases of human infections in industrialized countries.

This technology is a recombinant, infectious genotype 3 HEV that has been adapted to grow in cell culture and can potentially be used to develop vaccines against HEV or as a vector system to insert exogenous sequences into HEV. The virus (strain Kernow-C1, genotype 3) originated from a chronically infected

human subject and was adapted to grow in human hepatoma cells. The adapted virus is unique in that it contains an insertion of a portion of a human ribosomal protein in Open Reading Frame 1 of the virus. Desired exogenous sequences could potentially be placed in lieu of the insert without inactivating the virus, making the subject technology a prospective HEV vector platform.

*Potential Commercial Applications:*

- Vaccine—An infectious, recombinant HEV genotype 3 cDNA clone that could potentially be developed into a vaccine candidate.

- HEV Vector Platform—Desired exogenous sequences can be inserted into the viral genome without inactivating the virus.

*Competitive Advantages:*

- Most of the HEV vaccines under development are subunit based while the subject technology could potentially be developed into a live, attenuated virus based vaccine.

- Ability to insert exogenous sequences into the viral genome without inactivating the virus makes this subject technology a potential HEV based vector platform.

*Development Stage:*

- Early-stage
- Pre-clinical
- In vitro data available

*Inventors:* Suzanne U. Emerson, Priyanka Shukla, Hanh T. Nguyen, and Robert H. Purcell (NIAID).

*Publication:* Shukla P, et al. Cross-species infections of cultured cells by hepatitis E virus and discovery of an infectious virus-host recombinant. Proc Natl Acad Sci U S A. 2011 Feb 8;108(6):2438–2443. [PMID 21262830].

*Intellectual Property:* HHS Reference No. E-074-2011/0—U.S. Provisional Patent Application No. 61/431,377 filed 10 Jan 2011.

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

*Collaborative Research Opportunities:*

The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize hepatitis E virus vaccines. For collaboration opportunities, please contact Wade Green, PhD at 301-827-0258 or [williamsa@niaid.nih.gov](mailto:williamsa@niaid.nih.gov).

**Diagnostic H5N1 Avian Influenza Virus Peptides**

*Description of Technology:* The recent spread of highly pathogenic H5N1 avian influenza viruses among poultry and transmission of these viruses to humans raises concerns of a potential influenza

pandemic. There is a need to track the spread of these viruses both in the animal and human populations to avert or reduce the impact of any potential influenza pandemic as well as to know the actual number (accurate surveillance) of people infected with H5N1, including individuals with subclinical H5N1 infection.

The subject technology is a specific combination of H5N1 peptides useful for assays to detect antibodies generated against a wide range of different H5N1 strains. The combination of peptides was able to specifically detect anti-H5N1 antibodies from serum samples of H5N1 survivors at early and later times post infection while excluding antibodies generated in individuals infected with other strains of influenza virus. Also, the peptides did not react with sera from individuals vaccinated with H5N1 vaccine, in contrast to the strain-specific detection of anti-H5N1 antibodies in sera from infected individuals. Immunoassays using the H5N1 peptide combination provide highly specific, sensitive and reproducible methods for diagnosing H5N1 infection in humans and animals.

*Potential Commercial Applications:* Diagnostics for influenza virus specific antibodies in humans and animals.

*Competitive Advantages:* High specificity, sensitivity, and reproducibility.

*Development Stage:* Data obtained from clinical samples can be provided upon request.

*Inventors:* Hana Golding and Surender Khurana (FDA).

*Intellectual Property:* HHS Reference No. E-093-2010/0—PCT Application No. PCT/US2011/032555 filed 14 Apr 2011.

*Related Technology:* HHS Reference No. E-236-2007/3—U.S. Patent Application No. 12/664,052 filed 10 Dec 2008.

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

Dated: October 4, 2011.

**Richard U. Rodriguez,**

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

[FR Doc. 2011-26338 Filed 10-11-11; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Center On Minority and Health Disparities Notice of Closed Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of the following meetings.

The meeting 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 materials, 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 Center on Minority Health and Health Disparities Special Emphasis Panel; NIMHD Health Disparities Research (R01).

*Date:* November 7–8, 2011.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Gaithersburg Marriott Washington Center, 9751 Washington Boulevard, Gaithersburg, MD 20878.

*Contact Person:* Maryline Laude-Sharp, PhD, Scientific Review Officer, National Institute on Minority Health and Health Disparities, National Institutes of Health, 6707 Democracy Blvd., MSC. 5465, Suite 800, Bethesda, MD 20892, (301) 451-9536, [mlaudesharp@mail.nih.gov](mailto:mlaudesharp@mail.nih.gov).

*Name of Committee:* National Center on Minority Health and Health Disparities Special Emphasis Panel; NIMHD Support for Conference and Scientific meetings (R13) 2012.

*Date:* November 14, 2011.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Maryline Laude-Sharp, PhD, Scientific Review Officer, National Institute on Minority Health and Health Disparities, National Institutes of Health, 6707 Democracy Blvd., MSC. 5465, Suite 800, Bethesda, MD 20892, (301) 451-9536, [mlaudesharp@mail.nih.gov](mailto:mlaudesharp@mail.nih.gov).

Dated: October 5, 2011.

**Jennifer S. Spaeth,**

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-26360 Filed 10-11-11; 8:45 am]

**BILLING CODE 4140-01-P**