305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Melissa Reisman, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Blood Establishment Computer System Validation in the User's Facility '' dated April 2013. The guidance document provides assistance to blood establishments in developing a blood establishment computer system validation program, consistent with recognized principles of software validation, quality assurance, and current good software engineering practices. The guidance document describes the requirements in Title 21 Code of Federal Regulations that apply to blood establishment validation of systems, and FDA's recommendations for the validation of systems. While the guidance may provide manufacturers of blood establishment computer software (BECS) with information about validation of computer systems in the user's facility, the guidance does not address the software manufacturer's validation responsibilities or the submission of a 510(k) premarket notification for BECS.

In the **Federal Register** of October 29, 2007 (72 FR 61171), FDA announced the availability of the draft guidance of the same title dated October 2007. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated October 2007.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 606.100(b) and 606.160 have been approved under OMB control number 0910–0116. The collections of information in 21 CFR 211.68 and 211.100 have been approved under OMB control number 0910–0139.

## III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*

## IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: March 21, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013–06865 Filed 3–25–13; 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.

**FOR FURTHER INFORMATION CONTACT:** 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.

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

*Description of Technology:* This technology is a recombinant, infectious genotype 3 Hepatitis E virus (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 can potentially be placed in lieu of the insert without inactivating the virus.

Infection by HEV is a relevant health issue in a number of developing countries and 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.

*Potential Commercial Applications:*

- 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–074–2011/2—PCT Application PCT/US2012/020830 filed 10 Jan 2012.

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

*Collaborative Research Opportunity:* 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 Maryann Puglielli, Ph.D., J.D. at 301–451–6863 or *maryann.puglielli@nih.gov.*

**Composite Probes and Use Thereof in Super Resolution Microscopy**

*Description of Technology:* The technology is in the field of fluorescence microscopy. More specifically, the invention describes and claims the compo site probes for super resolution optical techniques using super resolution via transiently activated quenchers (STAQ). The compo site probes include a donor moiety and an acceptor moiety joined by a linker. The acceptor moiety, when excited by incident radiation, is excited to a state which, for example, absorbs in the donor emission region, such that the acceptor moiety in its excited state quenches at least a portion of the donor moiety emission. Other transiently activated quenching mechanisms and moieties could accomplish the same task by reducing donor population. Also disclosed are methods for irradiating a selected region of a target material including the compo site probe, wherein the compo site probe enables improved resolution by point spread function modification.

*Potential Commercial Applications:*

• Ultrafine imaging for biomolecules, vesicles and organelles, particularly of living biological samples, in biomedical research.
• Potential applications in clinical diagnostics.
• Nanoscopic Lithography—STAQ compo sites could, in principle, control polymerization of photoresist masks to make feature sizes below 20nm.

*Competitive Advantages:* Improved ultrafine imaging—

• Imaging objects as small as 10 nm.
• Narrow the point spread function.
• STAQ uses less power, making live cell study practical at theoretically high resolution.

*Development Stage:*

• The invention is fully developed.
• Need to build multicolor palette that can be integrated into a commercial microscope.
• May need to make certain protein chimeras and photoinitiators for validation.

*Inventors:* Jay R Knutson and Gary L. Griffiths (NHLBI).

*Publications:*

1. Doose S, et al. Probing polyproline structure and dynamics by photoinduced electron transfer provides evidence for deviations from a regular polyproline type II helix. Proc Natl Acad Sci USA. 2007 Oct 30;104(44):17400–5. [PMID 17956989]
2. Schuler B, et al. Polyproline and the ''spectroscopic ruler'' revi sited with single-molecule fluorescence. Proc Natl Acad Sci USA. 2005 Feb 22;102(8):2754–9. [PMID 15699337]
3. Best RB, et al. Effect of flexibility and cis residues in single-molecule FRET studies of polyproline. Proc Natl Acad Sci USA. 2007 Nov 27;104(48):18964–9. [PMID 18029448]
4. Sahoo H, et al. A 10–A spectroscopic ruler applied to short polyprolines. J Am Chem Soc. 2007 Aug 8;129(31):9762–72. [PMID 17629273]
5. Li L, et al. Achieving lambda/20 resolution by one-color initiation and deactivation of polymerization. Science. 2009 May 15;324(5929):892–3. [PMID 19359543]
6. Hell SW. Far-field optical nanoscopy. Science. 2007 May 25;316(5828):1153–8. [PMID 19525330]
7. Masia F, et al. Resonant four-wave mixing of gold nanoparticles for three-dimensional cell microscopy. Opt Lett. 2009 Jun 15;34(12):1816–8. [PMID 19529713]
8. Schmidt R, et al. Mitochondrial cristae revealed with focused light. Nano Lett. 2009 Jun;9(6):2508–10. [PMID 19459703]

*Intellectual Property:* HHS Reference No. E–253–2009/0—U.S. Patent Application No. 13/519,737 filed 28 Jun 2012

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

*Collaborative Research Opportunity:* The National Heart, Lung and Blood Institute, Laboratory of Molecular Biophysics, is also seeking statements of capability or interest from parties interested in collaborative partnerships to further develop, evaluate, or commercialize this technology. Please contact Brian Bailey, Ph.D. at *bbailey@mail.nih.gov* for more information.

Dated: March 18, 2013.

**Richard U. Rodriguez,**

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

[FR Doc. 2013–06836 Filed 3–25–13; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

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 meeting.

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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Operation of a Facility for Testing Malaria Vaccine in Human Subjects.

*Date:* April 19, 2013.

*Time:* 11:30 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

*Contact Person:* Jay R. Radke, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–496–2550, *jay.radke@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: March 20, 2013.

**David Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2013–06803 Filed 3–25–13; 8:45 am]

**BILLING CODE 4140–01–P**