

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered to this population, or the program planner or qualified person reasonably could have believed the recipient was in this population.

XI. Geographic Area

42 U.S.C. 247d-6d(a)(4), 247d-6d(b)(2)(D)

Liability immunity is afforded for the administration or use of a Covered Countermeasure without geographic limitation.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered in any designated geographic area; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered in any designated geographic area, or the program planner or qualified person reasonably could have believed the recipient was in that geographic area.

XII. Effective Time Period

42 U.S.C. 247d-6d(b)(2)(B)

Liability immunity for Covered Countermeasures began on February 27, 2015, and extends through February 26, 2019.

XIII. Additional Time Period of Coverage

42 U.S.C. 247d-6d(b)(3)(B) and (C)

I have determined that an additional 12 months of liability protection is reasonable to allow for the manufacturer(s) to arrange for disposition of the Covered Countermeasure, including return of the Covered Countermeasures to the manufacturer, and for Covered Persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasures.

Covered Countermeasures obtained for the SNS during the effective period of this Declaration are covered through the date of administration or use pursuant to a distribution or release from the SNS.

XIV. Countermeasures Injury Compensation Program

42 U.S.C 247d-6e

The PREP Act authorizes the Countermeasures Injury Compensation

Program (CICP) to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of the Covered Countermeasures, and benefits to certain survivors of individuals who die as a direct result of the administration or use of the Covered Countermeasures. The causal connection between the countermeasure and the serious physical injury must be supported by compelling, reliable, valid, medical and scientific evidence in order for the individual to be considered for compensation. The CICP is administered by the Health Resources and Services Administration, within the Department of Health and Human Services. Information about the CICP is available by telephone at 855-266-2427 (toll-free) or <http://www.hrsa.gov/cicp/>.

XV. Amendments

42 U.S.C. 247d-6d(b)(4)

Any amendments to this Declaration will be published in the **Federal Register**.

Authority: 42 U.S.C. 247d-6d.

Dated: December 2, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016-29609 Filed 12-9-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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 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: Center for Scientific Review Special Emphasis Panel; Neurogastroenterology.

Date: December 14, 2016.

Time: 9:00 a.m. to 10:00 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call)

Contact Person: Ganesan Ramesh, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Room 2182, MSC 7818, Bethesda, MD 20892, ganesan.ramesh@nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 6, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-29603 Filed 12-9-16; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Eye Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 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 Advisory Eye Council.

Date: January 19, 2017.

Open: 8:30 a.m. to 1:00 p.m.

Agenda: Following opening remarks by the Director, NEI, there will be presentations by the staff of the Institute and discussions concerning Institute programs.

Place: Terrace Level Conference Rooms, 5635 Fishers Lane, Rockville, MD 20852.

Closed: 1:00 p.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.

Place: Terrace Level Conference Rooms, 5635 Fishers Lane, Rockville, MD 20852.

Contact Person: Paul A. Sheehy, Ph.D., Director, Division of Extramural Affairs, National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 1300, Bethesda, MD 20892, 301-451-2020, ps32h@nih.gov.

Information is also available on the Institute's/Center's home page: www.nei.nih.gov, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: December 6, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-29604 Filed 12-9-16; 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, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing 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 application listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Zika Virus Vaccines

Description of Technology

Zika virus (ZIKV) is a flavivirus transmitted by mosquitos that is

strongly linked to neurological complications including Guillain-Barré syndrome, meningoencephalitis, and microcephaly. The association between active ZIKV infection during pregnancy and microcephaly and intrauterine growth retardation in the fetus has been confirmed in murine models of ZIKV infection.

Scientists at NIAID have developed nucleic acid-based vaccine candidates to prevent ZIKV infection in humans. The current lead candidate vaccine is a plasmid DNA vaccine demonstrated to accord protection in preclinical models and is undergoing clinical trial evaluation. Nucleic acid-based vaccines have been developed previously for West Nile virus, another flavivirus similar to Zika (J.E. Ledgerwood, et al. *J. Infect. Dis.* (2011) 203 (10): 1396–1404). Immunization with the nucleic acid ZIKV vaccine candidate results in production of noninfectious virus like particles (VLPs) made of ZIKV proteins. These ZIKV VLPs elicit an immune response which includes neutralizing antibodies to ZIKV.

Other preclinical ZIKV vaccine candidates include mRNA, protein, and noninfectious VLPs.

NIAID is continuing development of these vaccine candidates. The DNA-based ZIKV vaccine candidate is currently in clinical trials. Consequently, for some fields of use, NIAID will evaluate a license applicant's capabilities and experience in advancing similar technologies through the regulatory process.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration. This technology is not eligible for NIH's start up license.

Potential Commercial Applications:

- Prevention of Zika virus infection

Competitive Advantages:

- There is currently no licensed Zika virus vaccine

Development Stage:

- Currently, DNA-based vaccine candidate in Phase I clinical trial
- Phase II clinical trial planned for early 2017 for DNA-based vaccine candidate
- Other candidates are in pre-clinical development

Inventors: Barney S. Graham (NIAID), Theodore C. Pierson (NIAID), Kimberly A. Dowd (NIAID), John R. Mascola (NIAID), Wing-Pui Kong (NIAID), Sung-Youl Ko (NIAID), Eun Sung Yang (NIAID), Wei Shi (NIAID), Lingshu Wang (NIAID), Christina R. Demaso (NIAID), Rebecca S. Pelc (NIAID),

Adrian Creanga (NIAID), Julie Ledgerwood (NIAID), William Schief (The Scripps Research Institute), Sebastian Ramisch (The Scripps Research Institute), Leda Castilho (Federal University of Rio de Janeiro)
Publications: K.A. Dowd, et al., *Science*, 354, 237–240 (2016).

DOI: 10.1126/science.aai9137.

Intellectual Property: U.S. Patent Application No. 62/396,613 filed September 19, 2016 (HHS Reference No. E-181-2016/0-US-01).

Licensing Contact: Dr. Amy Petrik, 240-627-3721; amy.petrik@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 Zika virus vaccine technologies. For collaboration opportunities, please contact Dr. Amy Petrik, 240-627-3721; amy.petrik@nih.gov.

Dated: December 5, 2016.

Suzanne Frisbie,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2016-29605 Filed 12-9-16; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs And Border Protection

Modification and Clarification of the National Customs Automation Program Tests Regarding Post-Summary Corrections and Periodic Monthly Statements

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: General notice.

SUMMARY: This document announces U.S. Customs and Border Protection's (CBP's) plan to modify and clarify the National Customs Automation Program (NCAP) test pertaining to the processing of post-summary correction (PSC) claims to entry summaries that are filed in the Automated Commercial Environment (ACE), as well as the periodic monthly statement (PMS) test. The modifications made by this notice eliminate some requirements and liberalize certain requirements needed for the filing of a PSC making it easier for importers to file a PSC for additional entry types, and allowing for additional time to make a deposit for duties, fees and taxes owed. With regard to the PMS