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.

X. Geographic Area

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.

XI. Effective Time Period
42 U.S.C. 247d–6d(b)(B)

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

XII. 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]

BILLING CODE 4150–28–P

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 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.

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 7618, 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.


Dated: December 6, 2016.

Natasha M. Copeland,
Program Analyst, Office of Federal Advisory Committee Policy.

BILLING CODE 4140–01–P
Zika virus (ZIKV) is a flavivirus transmitted by mosquitoes 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. Competitive Advantages:

- Prevention of Zika virus infection
- 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