DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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: National Center for Complementary and Integrative Health Special Emphasis Panel; NCCIH Training and Education Review Panel (CT).

Date: June 17th–18th, 2021.

Time: 10:00 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: NIH/NCCIH Democracy II, 6707 Democracy Blvd., Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Patrick Colby Still, Ph.D., Scientific Review Officer, Office of Scientific Review, Division of Extramural Activities, NCCIH/NHI, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892–5475, patrick stil@nih.gov (Virtual Meeting).

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: Peter Soukas, J.D., 301–496–2644; peter.soukas@nih.gov. Licensing information and copies of the patent applications 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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.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:

Recombinant Chimeric Bovine/Human Parainfluenza Virus 3 Expressing SARS-CoV-2 Spike Protein and Its Use

Description of Technology

Vaccines for SARS-CoV-2 are increasingly available under emergency use authorizations; however, indications are currently limited to individuals twelve (12) years or older. They also involve intramuscular immunization, which does not directly stimulate local immunity in the respiratory tract, the primary site of SARS-CoV-2 infection, shedding and spread. While the major burden of COVID–19 disease is in adults, infection and disease also occur in infants and young children, contributing to viral transmission. Therefore, the development of safe and effective pediatric COVID–19 vaccines is important. Ideally, a vaccine should be effective as a single dose, should induce mucosal immunity with the ability to restrict SARS-CoV-2 infection and respiratory shedding, and should easily coordinate with vaccines for other illnesses, such as HPIV3.

The live-attenuated vaccine candidates are based on a recombinant chimeric bovine/human parainfluenza virus 3 (rB/HPIV3) vector expressing prefusion-stabilized versions of the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS–CoV–2) Spike (S) protein. The B/HPIV3–SARS CoV–2 vaccine candidates are designed to be administered intranasally by drops or spray to infants and young children. The vaccines are expected to induce durable and broad systemic and respiratory mucosal immunity against SARS-CoV–2 and HPIV3.

Immunogenicity and protective efficacy against SARS-CoV–2 challenge was confirmed in experimental animals including non-human primates. Based on experience with this B/HPIV3 platform and other live-attenuated PIV vaccine candidates in previous pediatric clinical studies, the present candidates are anticipated to be well-tolerated in humans, including infants and young children, and are available for clinical evaluation. The National Institute of Allergy and Infectious Diseases has extensive experience and capability in evaluating live-attenuated respiratory virus vaccine candidates in pediatric clinical studies, including PIV vaccine candidates, and opportunity for collaboration exists.

This technology is available for nonexclusive 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.

Potential Commercial Applications

• Viral diagnostics
• Vaccine research

Competitive Advantages

• Ease of manufacture
• B cell and T cell activation
• Low-cost vaccines
• Intranasal administration/needle-free delivery

Development Stage

• In vivo data assessment (animal)

Inventors: Ursula Buchholz (NIAID), Shirin Munir (NIAID), Cyril Le Nouen (NIAID), Xueqiao Liu (NIAID), Cindy Luongo (NIAID), Peter Collins (NIAID).