**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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.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:**
Technology description follows.

**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).

**Intellectual Property:** HHS Reference No. E–239–2020–0—U.S. Provisional
Institutes of Health (NEI) Office of the Scientific Director (OSD) goal is to train the next generation of vision researchers and ophthalmologists. Trainees who participate in NEI research come with different levels of education (student, postbaccalaureate, predoctoral including graduate and medical students, postdoctoral fellows) and for different amounts of time (6 months to 5 years). Training at the NEI focuses on scientific and professional skill development. To enhance their chances of obtaining their ideal career, completing an annual Individual Development Plan (IDP) is an important step in helping a trainee’s career and professional development and is standard practice in graduate and postdoctoral education. An IDP is an effective tool for trainees to think about their career goals and skills needed to achieve them during their time at the NEI. Trainees work together with their research mentor to organize and summarize their research projects, consider career goals, and set training goals and expectations, both for the mentee and mentor.

This information collection request is to implement an electronic Individual Development Plan (eIDP). The data collected comes from a detailed questionnaire focused on responses to professional goals and expectations while they are at the NEI. It is expected that the trainees will complete the eIDP annually and by doing so, it will help enhance the effectiveness of their training by setting clear goals that can be monitored not only by the trainee themselves but also by their mentor, the Training Director, and their Administrative Officer. In addition to this eIDP, the system will also implement an electronic exit survey. The data collected comes from a detailed questionnaire focused on responses to questions focused on trainee mentoring and professional experiences at the NEI as well as their plans after they depart. It is expected that the trainees will complete the eIDP annually and by doing so, the NEI Training Program can learn about ways to improve career development opportunities for future trainees as well as learn more about trainee job choices to better advise fellows. Additionally, we can use the survey to help determine mentor effectiveness and help identify problems in mentoring at the NEI.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 450.