## 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., 301–594–8730; *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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.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.

#### Method of Vaccination With an Attenuated RSV Vaccine Formulation

*Description of Technology:* Acute respiratory infections during early childhood constitute a major human health burden. Human respiratory syncytial virus (RSV) is the most common and important viral cause of severe acute pediatric respiratory infections worldwide. Mortality due to RSV in the post-neonatal (28 days to 1 year old) population is second only to malaria. It is estimated that RSV causes 34 million lower respiratory tract infections, 4 million hospitalizations, and 66,000–199,000 deaths every year in children less than 5 years of age. Most mortality occurs in the developing world where clinical care is less accessible. Mortality is low in the developed countries, but the morbidity is substantial: In the United States alone, RSV is associated with an estimated 132,000–172,000 hospitalizations annually in children less than 5 years old. There is not yet available a vaccine or an effective antiviral drug suitable for routine use.

This application claims a method of vaccinating a human subject against Respiratory Syncytial Virus (RSV) by administering a composition comprising an immunogenic amount of a recombinant RSV particle to the subject. An embodiment of the composition comprising the recombinant RSV particle was evaluated as a live intranasal vaccine in adults, RSV-seropositive children and RSV-seronegative children. When results in RSV-seronegative children were compared to those achieved with the previous leading live attenuated RSV candidate vaccine, vaccine virus shedding was significantly more restricted, yet the post-vaccination RSV-neutralizing serum antibody achieved was significantly greater. Surveillance during the subsequent RSV season showed that several RSV-seronegative recipients had substantial rises of RSV-neutralizing serum antibodies indicative of exposure to RSV, and yet without reported RSV-associated illness, suggesting that the vaccine was protective yet primed for anamnestic responses to RSV. Thus, the composition comprising the recombinant RSV particle was intrinsically superior at eliciting protective antibody in the subjects. Surprisingly, a single dose of the composition was sufficient to provide the greater antibody response and protective effect in seronegative and/or RSV-naive infants and children of less than about 24 months of age. This was an unexpected result, as it is currently anticipated that vaccination against RSV using a live, attenuated RSV vaccine will require administration of multiple doses, at least two or three at a minimum, in a single vaccination season to provide protective result.

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.

*Potential Commercial Applications:*

- Viral therapeutics
- Viral diagnostics
- Vaccine research

*Competitive Advantages:*

- Ease of manufacture
- Adjuvant unnecessary
- Favorable safety profile in clinical trials

*Development Stage:*

- In vivo data assessment (human)

*Inventors:* Ursula Buchholz (NIAID), Peter Collins (NIAID).

*Intellectual Property:* HHS Reference No. E–067–2016–0 —U.S. Provisional Application Nos. 62/251,030, filed November 4, 2015, 62/259,472, filed November 24, 2015, and 62/263,405, filed December 4, 2015, PCT Patent Application Number PCT/US2016/060672, filed November 4, 2016, European Patent Application Number 1694904.9, filed November 4, 2016 (pending), United States Patent Application Number 15/773,653, filed May 4, 2018 (pending).

*Licensing Contact:* Peter Soukas, J.D., 301–594–8730; *peter.soukas@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 for development of a vaccine for respiratory or other infections. For collaboration opportunities, please contact Peter Soukas, J.D., 301–594–8730; *peter.soukas@nih.gov.*

Dated: March 10, 2020.

**Wade W. Green,**

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

[FR Doc. 2020–05294 Filed 3–13–20; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

### Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer at (240) 276–0361.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on