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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.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

respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: National Survey of Substance Abuse Treatment Services (N–SSATS) (OMB No. 0930–0106)—Extension

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting an extension of the National Survey of Substance Abuse Treatment (N–SSATS) data collection (OMB No. 0930–0106), which expires on September 30, 2020. N–SSATS provides both national and state-level data on the numbers and types of patients treated and the characteristics of facilities providing substance abuse treatment services. It is conducted under the authority of Section 505 of the Public Health Service Act (42 U.S.C. 290aa–4) to meet the specific mandates for annual information about public and private substance abuse treatment providers and the clients they serve.

This request includes:

- Collection of N–SSATS, which is an annual survey of substance abuse treatment facilities; and
- Updating of the Inventory of Behavioral Health Services (I–BHS) which is the facility universe for the N–SSATS. I–BHS is also the facility universe for the annual survey of mental health treatment facilities, the National Mental Health Services Survey (N–MHSS). The I–BHS includes all substance abuse treatment and mental health treatment facilities known to SAMHSA. (The N–MHSS data collection is covered under OMB No. 0930–0119.)

The information in I–BHS and N–SSATS is needed to assess the nature and extent of these resources, to identify gaps in services, and to provide a database for treatment referrals. Both I–BHS and N–SSATS are components of the Behavioral Health Services Information System (BHSIS).

The request for OMB approval will include a request to update the I–BHS facility listing on a continuous basis and to conduct the N–SSATS and the between cycle N–SSATS (N–SSATS BC) in 2021, 2022, and 2023. The N–SSATS BC is a procedure for collecting services data from newly identified facilities between main cycles of the survey and will be used to improve the listing of treatment facilities in the online Behavioral Health Treatment Services Locator.

Estimated annual burden for the BHSIS activities is shown below:

Type of respondent and activity	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
States					
I–BHS Online [1]	56	75	4,200	0.08	336
State Subtotal	56		4,200		336
Facilities					
I–BHS application [2]	800	1	800	0.08	64
Augmentation screener	1,300	1	1,300	0.08	104
N–SSATS questionnaire	17,000	1	17,000	0.67	11,333
N–SSATS BC	1,000	1	1,000	0.58	580
Facility Subtotal	20,100		20,100		12,081
Total	20,156		24,300		12,417

[1] States use the I–BHS Online system to submit information on newly licensed/approved facilities and on changes in facility name, address, status, etc.

[2] New facilities complete and submit the online I–BHS application form in order to get listed on the Inventory.

Send comments to Carlos Graham, SAMHSA Reports Clearance Officer, 5600 Fisher Lane, Room 15E57A, Rockville, MD 20852 *OR* email him a copy at *carlos.graham@samhsa.hhs.gov.* Written comments should be received by May 15, 2020.

Carlos Graham,

Social Science Analyst.

[FR Doc. 2020–05274 Filed 3–13–20; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

Determination Pursuant to Section 102 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, as Amended

AGENCY: Office of the Secretary, Department of Homeland Security.

ACTION: Notice of determination.

SUMMARY: The Acting Secretary of Homeland Security has determined, pursuant to law, that it is necessary to waive certain laws, regulations, and other legal requirements in order to ensure the expeditious construction of barriers and roads in the vicinity of the international land border in Val Verde County, Texas, and Maverick County, Texas.

DATES: This determination takes effect on March 16, 2020.

SUPPLEMENTARY INFORMATION: Important mission requirements of the Department of Homeland Security (''DHS'') include border security and the detection and prevention of illegal entry into the United States. Border security is critical to the nation's national security. Recognizing the critical importance of border security, Congress has mandated DHS to achieve and maintain operational control of the international land border. Secure Fence Act of 2006, Public Law 109–367, section 2, 120 Stat. 2638 (Oct. 26, 2006) (8 U.S.C. 1701 note). Congress defined ''operational control'' as the prevention of all unlawful entries into the United States, including entries by terrorists, other