

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: Jenish Patel, Ph.D., 240-669-2894; jenish.patel@nih.gov. Licensing information and copies of the U.S. patent application 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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.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.

Broadly Protective Influenza Vaccine Comprising a Cocktail of Inactivated Avian Influenza Viruses

Description of Technology: There is a great need for broadly protective, “universal” influenza virus vaccines given the antigenic drift and shift of influenza viruses and the variable protective efficacy of the current influenza vaccines. This technology relates to a broadly protective, “universal” influenza vaccine candidate composed of a cocktail of different low pathogenicity avian influenza virus subtypes inactivated by betapropiolactone (BPL). Vaccinating animals with BPL-inactivated whole virus vaccine comprising influenza virus strains belonging to four or more different low pathogenicity avian influenza hemagglutinin subtypes, intranasally or intramuscularly, provided extremely broad protection and heterosubtypic protection to lethal challenge with influenza viruses in both mice and ferrets. This influenza vaccine technology has a great potential to offer broad protection against both seasonal

and pandemic-potential influenza viruses.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404.

Potential Commercial Applications:

- Vaccine against viruses
- Vaccines against influenza virus
- Universal influenza virus vaccine

Competitive Advantages:

- Broad protection to both seasonal and pandemic-potential influenza viruses
- Easy and cost-effective inactivation method
- Effective immune response due to the use of authentic viral antigens
- Animal data available

Development Stage:

- In vivo (animal)

Inventors: Jeffery K. Taubenberger, M.D., Ph.D., (NIAID) and Louis Merican Schwartzman, Ph.D. (NIAID).

Publications: None.

Intellectual Property: HHS Reference No. E-033-2018/0—PCT Application filed January 18, 2019—PCT/US2019/014220.

Licensing Contact: To license this technology, please contact Jenish Patel, Ph.D., 240-669-2894; jenish.patel@nih.gov.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is also seeking statements of capability or interest from parties interested in collaborative research. NIAID would like a prospective collaborator to have the capacity to generate clinical grade materials and perform clinical studies. NIAID will consider executing a Confidentiality Agreement with a prospective collaborator to facilitate receipt of a Capability Statement if requested. For collaboration opportunities, please contact Jenish Patel, Ph.D., 240-669-2894; jenish.patel@nih.gov.

Dated: November 27, 2019.

Wade W. Green,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Submission for OMB Review; 30-Day Comment Request; Autism Spectrum Disorder (ASD) Research Portfolio Analysis, NIMH**

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: The Office of Autism Research Coordination, NIMH, NIH, Neuroscience Center, 6001 Executive Boulevard, MSC 9663, Room 6184, Bethesda, Maryland 20892 or can email your request, including your address to: iaccpublicinquiries@mail.nih.gov or nimhprapubliccomments@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on October 3, 2019, page 52888 (84 FR 52888) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Mental Health (NIMH), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or