

Dated: March 9, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-05094 Filed 3-12-20; 8:45 am]

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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.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

Genomic Sequence of Avian Paramyxovirus Type 2 and Uses Thereof

Description of Technology

As a first step towards characterizing the molecular genetics and pathogenesis of avian paramyxovirus type 2 (APMV-2), the biological activities and growth characteristics of APMV-2 were investigated. The present inventors found that APMV-2 is different than Newcastle Disease Virus (NDV, AMPV-1) in several characteristics: (I) APMV-2 does not require trypsin or allantoic fluid to grow in cell culture; (II) previous RNA-RNA hybridization studies showed APMV-2 is genetically different than NDV; (III) APMV-2 is the only paramyxovirus serotype which causes single-cell infection foci in cell

culture, and does not induce cell fusion, which is a hallmark of paramyxovirus infection; (IV) APMV-2 does not kill chicken embryos; and (V) APMV-2 does not grow in the brain of chickens.

These results suggested that APMV-2 is significantly different biologically and genetically from NDV. These differences provide certain advantages over other viruses considered for use as a vaccine, as a virus vector, or as a therapeutic. For example, unlike the current NDV vaccine such as LaSota and Hitchner B1 that can cause disease due to reversion to virulence, since AMPV-2 is not an agricultural pathogen, it is not a concern for the poultry industry. Unlike many strains of NDV, APMV-2 is not a Select Agent.

However, in order to develop a recombinant APMV-2 virus for use as a vector, vaccine, or cancer therapy, the complete genome sequence was needed, and a reverse genetic system needed to be developed. Sequence analysis proved to be difficult since primers based on NDV were not useful because the two viruses are genetically different. Therefore, different strategies had to be used for primer design, including the design and testing of consensus primers from other paramyxoviruses, primers based on gene start and gene end sequences of other paramyxoviruses, and primer walking.

This invention covers the complete genomic sequence of avian paramyxovirus type 2, strains Yucaipa, England, Kenya and Bangor. The genomic sequence of strain Yucaipa was used to develop a reverse genetic system for AMPV-2. This produced cDNA-derived AMPV-2 with the same properties as biologically-derived AMPV-2, confirming the authenticity of the genomic sequence. The sequence and reverse genetic system are useful for production of recombinant infective virus, a virus vector, for vaccine development and for therapeutic compositions. The sequences are also useful for development of viral diagnostics. The recombinant APMV-2 was used to express a foreign antigen, the green fluorescent protein (GFP), and can be used as a vaccine vector. Recombinant APMV-2 can also be used in cancer treatment, similar to NDV.

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
- Low-cost vaccine
- Adjuvants unnecessary

Development Stage

- In vivo data assessment (animal)

Inventors: Siba Samal (EM), Peter Collins (NIAID).

Intellectual Property: HHS Reference No. E-019-2018-0—U.S. Provisional Application No. 61/218,851, filed June 19, 2009, HHS Reference No. E-019-2018-1—U.S. Patent Application No. 12/803165, filed June 21, 2010, now U.S. Patent No. 9,937,196.

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 2, 2020.

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; Generic Clearance for NIH Citizen Science and Crowdsourcing Projects (Office of the Director)

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: Mikia Currie, Chief, Project Clearance Branch (PCB), Office of Policy and Extramural Research Administration (OPERA), Office of the Director (OD), Office of Extramural Research (OER), NIH, 6705 Rockledge Drive, Bethesda, Maryland 20892, MSC 7980, or call non-toll-free number (301) 435-0941 or Email your request, including your address to: *ProjectClearanceBranch@mail.nih.gov*.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on October 4, 2019, page 53162 (84 FR 53162) 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 Project Clearance Branch (PCB), Office of Policy and Extramural Research Administration (OPERA), Office of the Director (OD), Office of Extramural Research (OER), 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 after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of 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.

Proposed Collection: Generic Clearance for NIH Citizen Science and Crowdsourcing Projects—0925–New—XX/XX/XXXX, Project Clearance Branch (PCB), Office of Policy and Extramural Research Administration (OPERA), Office of the Director (OD), Office of Extramural Research (OER), National Institutes of Health (NIH).

Need and Use of Information Collection: Projects under this generic

clearance will allow Agency researchers and program staff to test ideas more quickly, respond to the project’s needs as they evolve, and incorporate feedback from participants for flexible, innovative research methods. The purpose of this information collection is to:

- Accelerate scientific research
- Increase cost-effectiveness to maximize the return on taxpayer dollars
- Address societal needs
- Provide hands-on learning in STEM education
- Connect members of the public directly to federal science missions and each other
- Identify and disseminate resources more broadly to the public, on the Institutes’ and Centers’ (ICs) websites, and/or
- Collect information for agency internal use to improve scientific practices and/or assist in scientific reviews

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 18,584.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of collection	Number of respondents	Number of responses per respondent	Time per response (in hours)	Total hours
Call for Nominations/Resources	1,000	1	10/60	167
Recommendations of scientific reviewers	1,000	1	5/60	83
Request for Population Characteristics	20,000	1	5/60	1,667
Repository of Tools and Best Practices	100,000	1	10/60	16,667
Total	122,000	18,584

Dated: March 5, 2020.

Lawrence A. Tabak,
Deputy Director, National Institutes of Health.
 [FR Doc. 2020-05104 Filed 3-12-20; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental 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 Institute of Mental Health Special Emphasis Panel; NIMH Pathway to Independence Awards (K99/R00, K22).

Date: March 24, 2020.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: David W. Miller, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center,

6001 Executive Blvd., Room 6140, MSC 9608, Bethesda, MD 20892-9608, 301-443-9734, *millerda@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: March 9, 2020.

Melanie J. Pantoja,
Program Analyst, Office of Federal Advisory Committee Policy.

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