

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Category of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Individuals (DARF-Oral)	711	16	4/60	758
Total	2,844	45,504	3,033

Patricia M. Busche,

Project Clearance Liaison, National Cancer Institute, National Institutes of Health.

[FR Doc. 2018–23313 Filed 10–24–18; 8:45 am]

BILLING CODE 4140–01–P

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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.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

Recombinant Respiratory Syncytial Virus Challenge Strain

Description of Technology

RSV is the most important viral agent of severe respiratory tract disease worldwide, especially in infants and young children, and it also causes severe disease in the elderly and in immunocompromised individuals. There are no licensed vaccines or antivirals suitable for routine use.

This invention relates to a reverse genetics system and cDNA-derived virus for a contemporary wild-type clinical isolate of RSV of antigenic subgroup A, termed RSV strain A/Maryland/001/11, that was isolated in 2011 from an adult with respiratory illness. The genomic sequence was determined. A reverse genetics system was created encoding a recombinant, replication competent RSV that contains a codon-optimized G ORF, which was done to stabilize the cDNA for replication in bacteria. Because this virus was generated by reverse genetics, it is a “clean” virus with a well-defined passage history. Clinical study material of this challenge virus has been manufactured and is available for use as an U.S. Food and Drug Administration (FDA) regulated Investigational New Drug (IND) in clinical studies in adult volunteers within and outside of the United States. Preliminary clinical data confirmed that this virus efficiently infects and replicates in 95% of study participants pre-selected for pre-existing RSV antibody titers in the bottom 50% of the range. The challenge virus causes mild upper respiratory illness in the majority of infected participants, typical for RSV illness in otherwise healthy adults. This provides a suitable challenge system for evaluating antivirals, as well as vaccines for older children and adults. This also could be used for developing live-attenuated RSV vaccine candidates based on this contemporary strain, using the stabilized point mutations, stabilized codon-deletions, and gene-deletions that were previously used in RSV strain A2.

This invention relates to a reverse genetics system and the encoded RSV vaccine challenge strain that infects and causes disease in RSV-experienced adults and is available for antiviral and vaccine research.

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

- Vaccine development
- Viral diagnostics

- Vaccine research

Competitive Advantages

- Ease of manufacture
- Clinical trial material
- Low-cost vaccines
- Intranasal administration/needle-free delivery

Development Stage

- In vivo data assessment (human)
Inventors: Ursula Buchholz (NIAID), Peter Collins (NIAID).

Intellectual Property: HHS Reference No. E–235–2018–0.

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: October 12, 2018.

Suzanne M. Frisbie,

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

[FR Doc. 2018–23311 Filed 10–24–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Chronic Disease and Epidemiology.

Date: November 1, 2018.

Time: 11:00 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Delia Olufokunbi Sam, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3158, MSC 7770, Bethesda, MD 20892, 301-435-0684, olufokunbisamd@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; AIDS and Related Research.

Date: November 9, 2018.

Time: 9:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Barna Dey, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, Bethesda, MD 20892, 301-451-2796, bdey@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Review of Aging Applications.

Date: November 20, 2018.

Time: 1:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Seetha Bhagavan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892, (301) 237-9838, bhagavas@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR-18-727: Molecular Profiles and Biomarkers of Food and Nutrient Intake.

Date: November 20, 2018.

Time: 1:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Gregory S. Shelness, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6156, Bethesda, MD 20892-7892, (301) 435-0492, shelnessgs@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 18, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-23265 Filed 10-24-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Office of AIDS Research Advisory Council.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Office of AIDS Research Advisory Council.

Date: November 15, 2018.

Time: 8:30 a.m. to 4:30 p.m.

Agenda: The forty-ninth OARAC meeting will include review of the DHHS HIV/AIDS Treatment and Prevention Guidelines; the OAR Director's Report; updates on the OAR cost sharing activities with the National Institute on Aging, the FY2019/2020 Trans-NIH Plan for HIV-Related Research; other HIV/AIDS research activities across selected NIH Institutes; and public comment.

Place: National Institutes of Health, Conference Room 1D13, 5601 Fishers Lane, Rockville, MD 20892.

Contact Person: Jay R. Radke, Ph.D., Scientific Review Officer, Office of AIDS Research, National Institutes of Health, Ofc of the Director, 5601 Fishers Lane, Room 2E61 MSC-9834, Bethesda, MD 20892-9834, (240) 669-5046, jay.radke@nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: www.oar.nih.gov, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate

Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: October 19, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-23263 Filed 10-24-18; 8:45 am]

BILLING CODE 4140-01-P

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.

Use of Rostafuroxin To Inhibit Viral Infection

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.