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 Neurological Disorders and Stroke Special Emphasis Panel; NINDS Diversity Training Grant Application Review.

Date: November 16, 2018.

Time: 12:00 p.m. to 6:00 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: William C. Benzing, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3204, MSC 9529, Bethesda, MD 20892–9529, (301) 496–0660, *benzingw@mail.nih.gov*.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Blueprint Neurotherapeutics Review Meeting.

Date: November 28, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Georgetown Suites, 1111 30th Street NW, Washington, DC 20007.

Contact Person: Joel A. Saydoff, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3205, MSC 9529, Bethesda, MD 20892–9529, (301) 496–9223, *joel.saydoff@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: October 18, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–23264 Filed 10–24–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Investigational Agent Accountability Record Forms in the Conduct of Investigational Trials for the Treatment of Cancer (National Cancer Institute)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Charles Hall, Chief, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, Division of Cancer Diagnosis and Treatment, National Cancer Institute, 9609 Medical Center Drive, Bethesda, Maryland, 20892 or call non-toll-free number (240) 276–6575 or Email your request, including your address to: *HallCh@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimizes the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Investigational Agent Accountability Record Forms in the Conduct of Investigational Trials for the Treatment of Cancer, 0925–0613, Expiration Date 3/31/2019, Revision, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The U.S. Food and Drug Administration (FDA) holds the National Cancer Institute (NCI), Division of Cancer Treatment and Diagnosis/Cancer Therapy Evaluation Program (NCI/DCTD/CTEP) and the Division of Cancer Prevention (DCP) responsible, as a sponsor of investigational drug trials, to assure the FDA that systems for accountability are being maintained by investigators in its clinical trials program. Data obtained from the Investigational Agent Accountability Record Forms (aka. Drug Accountability Record Forms—DARF) are used to track the dispensing of investigational anticancer agents from receipt from the NCI to dispensing or administration to patients. Requirements for the tracking of investigational agents under an Investigational New Drug Application are outlined in Title 21 Code of Federal Regulations (CRF) part 312. NCI and/or its auditors use this information to ensure compliance with federal regulations and NCI policies. Previously, the investigator registration forms and process were part of this submission. These forms were more appropriately submitted and approved under the CTEP Branch and Support Contracts Forms and Surveys in July 2018 (OMB No. 0925–0753; Expiration Date 7/31/2021). Thus, the investigator registration forms are no longer included in this request.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden are 3,033 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Category of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Individuals (DARF)	2,133	16	4/60	2,275

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