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 minimize 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.

ESTIMATED ANNUALIZED BURDEN HOURS

<table>
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<th>Category of respondent</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average time per response (in hours)</th>
<th>Total annual burden hours</th>
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</thead>
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<td>16</td>
<td>4/60</td>
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</table>
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

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

**Development Stage**
- In vivo data assessment (human)
- In vitro data assessment (animal or cell)
- Pre-clinical studies (animal models)
- Clinical trial material
- Confidential Disclosure Agreement

**Viral diagnostics**
- In vivo testing
- In vitro testing
- Pre-clinical testing
- Clinical trials

**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.

**SUPPLEMENTARY INFORMATION:**

Technology description follows.

**Availability for Licensing**

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.

**SUPPLEMENTARY INFORMATION:**

Technology description follows.

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**SUPPLEMENTARY INFORMATION:**

Communications could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning