

expertise outside the federal government. Additional information about ICCVAM can be found at <http://ntp.niehs.nih.gov/go/iccvam>.

NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts and publishes analyses and evaluations of data from new, revised, and alternative testing approaches. NICEATM and ICCVAM work collaboratively to evaluate new and improved testing approaches applicable to the needs of U.S. federal agencies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative testing approaches for validation studies and technical evaluations. Additional information about NICEATM can be found at <http://ntp.niehs.nih.gov/go/niceatm>.

Dated: August 16, 2016.

**John R. Bucher,**

*Associate Director, National Toxicology Program.*

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**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 and/or co-development in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 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 and/or co-development.

**ADDRESSES:** Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD 20850-9702.

**FOR FURTHER INFORMATION CONTACT:** Information on licensing and co-development research collaborations, and copies of the U.S. patent applications listed below may be obtained by contacting: Attn. Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center

Drive, Mail Stop 9702, Rockville, MD 20850-9702, Tel. 240-276-5515 or email [ncitechtransfer@mail.nih.gov](mailto:ncitechtransfer@mail.nih.gov). A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

#### **SUPPLEMENTARY INFORMATION:**

Technology description follows.

*Title of invention:* Methods of Analyzing Virus-Derived Therapeutics.

*Description of Technology:* Researchers at the National Cancer Institute's Biopharmaceutical Development Program recently developed massively parallel sequencing methods for virus-derived therapeutics such as viral vaccines and oncolytic immunotherapies. The methods allow for the determination of micro-heterogeneity and quantitation of low frequency sequence variants, which have the possibility of supplanting monkey neurovirulence safety testing (MNVT), mutant analysis by PCR, and restriction enzyme cleavage (MAPREC) methods that are currently used to screen RNA virus-derived therapeutics.

*Potential Commercial Applications:*

- Improved methods for detecting mutations in GMP-manufactured virus-derived therapeutics, including viruses, viral template plasmids, or vaccines;
  - The method allows for at least two different virus-derived therapeutics to be assayed simultaneously.
- Value Proposition:*
- Provides a cost- and time-effective means of assaying a virus-derived therapeutic, such as oncolytic viruses, for viral sequence variants, for regulatory approval;
  - RNA virus preparation steps increase the amount of viral RNA obtained;
  - Demonstrated superiority of massively parallel sequencing ("MPS") over mutant analysis by PCR and restriction enzyme cleavage ("MAPREC") analysis.

*Development Stage:* Clinical Phase I.

*Inventor(s):* Trevor Broadt (NCI), Michael D. Harwich (American International Biotechnology, LLC), William T. Budd (American International Biotechnology, LLC), Gregory A. Myers (American International Biotechnology, LLC).

*Intellectual Property:*

HHS Ref. No. E-240-2015/0-U.S.-01, corresponding to U.S. Provisional Patent App. No. 62/199,663, filed July 31, 2015/62/173,777, entitled "Methods of Analysis of RNA Virus-Derived Therapeutics"

HHS Ref. No. E-240-2015/0-PCT-02, corresponding to International Patent App. No. PCT/US2016/044788, filed July 29, 2016, entitled "Methods of

Analyzing Virus-Derived Therapeutics"

*Related Technologies:* HHS Reference #E-267-2014/0 entitled "Processes for Production and Purification of Nucleic Acid Containing Compositions".

*Contact Information:* Requests for copies of the patent application or inquiries about licensing, research collaborations, and co-development opportunities should be sent to John D. Hewes, Ph.D., email: [john.hewes@nih.gov](mailto:john.hewes@nih.gov).

Dated: August 16, 2016.

**John D. Hewes,**

*Technology Transfer Specialist, Technology Transfer Center, National Cancer Institute.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.