

OS specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Terry S. Clark,

Asst Information Collection Clearance Officer.

[FR Doc. 2016-20158 Filed 8-23-16; 8:45 am]

BILLING CODE 4150-37-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Child Health and Human Development Special Emphasis Panel, Developmental Mechanisms of Human Structural Birth Defects.

Date: September 20, 2016.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge 6710B, 6710B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Sherry L Dupere, Ph.D., Chief, Scientific Review Branch, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710 B Rockledge Drive, Room 2115, Bethesda, MD 20892-7510, 301-451-3415, duperes@mail.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and

Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: August 18, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-20150 Filed 8-23-16; 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 (5 U.S.C. App.), 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; Shared and High-End Instrumentation: Crystallography and NMR.

Date: September 20, 2016.

Time: 8:00 a.m. to 6:00 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: Michael Eissenstat, Ph.D., Scientific Review Officer, BCMB IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4166, Bethesda, MD 20892, 301-435-1722, eissenstatma@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Shared and High-End Instrumentation: Crystallography and NMR.

Date: September 20, 2016.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Sudha Veeraraghavan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-435-1504, sudha.veeraraghavan@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: August 17, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-20151 Filed 8-23-16; 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 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. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Title of invention: Processes for Producing and Purifying Nucleic Acid-Containing Compositions.

Description of Technology: This technology consists of improved processes for producing and purifying nucleic acid-containing compositions, such as non-naturally occurring viruses, for example, recombinant polioviruses that can be used as oncolytic agents. Some of the improved processes relate

to producing viral DNA templates and for chromatographic purification of nucleic acid-containing compositions, in which the nucleic acid is quantified in chromatography fractions with the rapid detection of one or more nucleic acid sequences (e.g., using real time RT-qPCR detection). In addition, the invention includes improved processes for production and purification of oncolytic poliovirus, such as PVSRIPO. Compositions generated using these methods are also described.

Potential Commercial Applications:

- Large-scale manufacturing for producing highly purified, live virus.
- Improved viral purification process that:

- Increases the yield and/or purity of the resulting product, while decreasing the purification time;
- is generally applicable to purification of any nucleic acid molecule-containing composition, such as virus-based composition, and can be used for the purification of live native or recombinant viruses necessary for clinical applications.

- Improved process for generating viral template plasmid (such as one that includes a DNA template for an RNA virus), which addresses the problem of genetic instability of the plasmids containing the viral genome (e.g., of a recombinant polio virus) in host (e.g., bacterial) cells, in which the plasmids are typically propagated.

Value Proposition:

- Cost- and time-effective means of producing highly purified virus-based GMP products, such as oncolytic viruses, for regulatory approval.

Development Stage: Clinical Phase I.

Inventor(s): Trevor Broadt (NCI), Samir Shaban (NCI), Yueqing Xie (NCI), Jianwei Zhu (NCI), George Mitra (NCI).

Intellectual Property: HHS Ref. No. E-267-2014/0-US-01, corresponding to US Provisional Patent App. No. 62/173,777, filed June 10, 2015, entitled "Processes for Production and Purification of Nucleic Acid Containing Compositions."

HHS Ref. No. E-267-2014/0-PCT-02, corresponding to International Patent App. No. PCT/US2016/036888, filed June 10, 2016, entitled "Processes for Production and Purification of Nucleic Acid Containing Compositions".

Publications: Ouellette *et al.*,

BioProcessing J. 2005 4(2):31-38.

Related Technologies: HHS Reference #E-240-2015/0 entitled "Methods of Analyzing Virus-Derived Therapeutics".

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.

Dated: August 16, 2016.

John D. Hewes,

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

[FR Doc. 2016-20160 Filed 8-23-16; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Interagency Coordinating Committee on the Validation of Alternative Methods Biennial Progress Report: 2014-2015; Availability of Report

SUMMARY: The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) announces availability of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Biennial Progress Report: 2014-2015. This report, prepared in accordance with requirements of the ICCVAM Authorization Act of 2000 (42 U.S.C. 285l-3), describes activities and accomplishments from January 2014 through December 2015.

ADDRESSES: The report is available at <http://ntp.niehs.nih.gov/iccvamreport/2015/index.html>.

FOR FURTHER INFORMATION CONTACT: Dr. Warren Casey, Director, NICEATM; email: warren.casey@nih.gov; telephone: (919) 316-4729.

SUPPLEMENTARY INFORMATION:

Background: The ICCVAM Authorization Act of 2000 established ICCVAM as a permanent interagency committee of the National Institute of Environmental Health Sciences (NIEHS) under NICEATM. ICCVAM's mission is to facilitate development, validation, and regulatory acceptance of new and revised regulatory test methods that reduce, refine, or replace the use of animals in testing while maintaining and promoting scientific quality and the protection of human health, animal health, and the environment.

A provision of the ICCVAM Authorization Act states that ICCVAM shall prepare "reports to be made available to the public on its progress under this Act." The eighth ICCVAM progress report is now available, which describes ICCVAM activities and accomplishments from January 2014 through December 2015.

Summary of Report Contents: Key ICCVAM, ICCVAM agency, and NICEATM accomplishments summarized in the report include:

- A computational approach that integrates several types of data to predict human skin sensitization hazard without using animals (ICCVAM)
- A plan to adopt high throughput assays and computational models for detecting and measuring estrogen receptor bioactivity as an alternative for three Tier 1 tests currently used in the Endocrine Disruptor Screening Program to assess estrogen receptor activity (U.S. Environmental Protection Agency [EPA])
- Establishment of a Communities of Practice webinar seminar series discussing relevant topics (ICCVAM)
- Evaluation of acute oral and dermal toxicity data to determine if oral toxicity tests are sufficient to assign U.S. EPA dermal hazard classifications, eliminating the need for separate acute dermal toxicity tests (NICEATM)
- A series of workshops that drafted recommendations on use of an *in vitro* test with potential to replace animal use for pertussis vaccine testing (NICEATM, U.S. Food and Drug Administration, other ICCVAM agencies).

Availability of Report: The report is available at <http://ntp.niehs.nih.gov/iccvamreport/2015/index.html>. Links to this report and all past ICCVAM annual and biennial reports are available at <http://ntp.niehs.nih.gov/go/iccvam-bien>.

Background Information on ICCVAM and NICEATM: ICCVAM is an interagency committee composed of representatives from 15 federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods and integrated testing strategies with regulatory applicability and promotes the scientific validation and regulatory acceptance of testing methods that more accurately assess the safety and hazards of chemicals and products and replace, reduce, or refine (enhance animal well-being and lessen or avoid pain and distress) animal use.

The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l-3) establishes ICCVAM as a permanent interagency committee of NIEHS and provides the authority for ICCVAM involvement in activities relevant to the development of alternative test methods. ICCVAM acts to ensure that new and revised test methods are validated to meet the needs of federal agencies, increase the efficiency and effectiveness and federal agency test method review, and optimize utilization of scientific