

other unwanted small molecules accumulate in the vessel with a potential to disrupt the cell growth, protein production, and the stability of the generated protein of interest. Second, necessary buffer exchange and/or cell concentration steps must be performed outside of the culturing vessel. These steps are more involved and increase the risk of contamination. Lastly, even with the addition of daily supplementation in the fed-batch process, there are limitations in length of time that the transfected cells remain viable and productive.

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases (NIAID) developed a new transient gene expression (TGE) bioprocess using a perfusion system that resolves the current fed-batch limitations for influenza vaccine production. The major components of this technology are two-fold: the optimization of conditions for polyethylenimine (PEI)-mediated gene transfection in the bioreactor without the interference of microbubbles; and the implementation of a perfusion-based alternating tangential flow (ATF) system for single-system, prolonged cell culture, combining the steps of cell concentration, waste clearance, culturing/media replenishment, and protein expression within a single vessel.

The development of the TGE bioprocess included optimization of conditions for HEK293 cell growth in the bioreactor, optimized transfection mediated by PEI, and protein expression for an extended period to achieve reproducibility and high protein yield.

Due to high improvement in cell growth and protein production without external handling, this bioprocess could lead to substantial cost saving and other benefits in vaccine and drug manufacturing of clinical grade materials.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404.

Potential Commercial Applications

- **Bioprocess**—A single-use protein production platform for transient gene expression (TGE) with potential applications in rapid protein expression as well as vaccine and drug manufacturing.

Competitive Advantages

The new transient gene expression (TGE) bioprocess for vaccine manufacturing has the following

features compared to commonly used related processes such as fed-batch:

- Robust, prolonged cell growth.
- High levels of protein production and reproducibility.

- Cost efficiency.
- Reduction in contamination risk.

Development Stage: Final Product.

Inventors: Jinsung Hong, Ph.D. (NIAID); Jacob Demirji, Ph.D. (NIAID); Daniel Blackstock, Ph.D. (NIAID); and Joe Horwitz, Ph.D. (NIAID).

Intellectual Property: HHS Reference Number E-187-2018 includes U.S. Provisional Patent Application Number 62/751,204 filed 10/26/2018.

Licensing Contact: To license this technology, please contact Dianca Finch, Ph.D., 240-669-5503; dianca.finch@nih.gov.

Dated: October 10, 2019.

Wade W. Green,

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

[FR Doc. 2019-25620 Filed 11-25-19; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Eye Council.

The meeting will be open to the public as indicated below, 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.

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 Advisory Eye Council.

Date: January 17, 2020.

Open: 8:30 a.m. to 12:00 p.m.

Agenda: Following opening remarks by the Acting Director, NEI, there will be

presentations by the staff of the Institute and discussions concerning Institute programs.

Place: National Eye Institute, 6700B Rockledge Drive, 1st Floor Conference Room, Bethesda, MD 20817.

Closed: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, 6700B Rockledge Drive, 1st Floor Conference Room, Bethesda, MD 20817.

Contact Person: Anne E. Schaffner, Ph.D., Chief, Scientific Review Branch, Division of Extramural Research, National Eye Institute, National Institutes of Health, 6700 B Rockledge Dr. Ste 3400, Bethesda, MD 20892-9300. (301) 451-2020, aes@nei.nih.gov.

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

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: November 21, 2019.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-25687 Filed 11-25-19; 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 Communities of Practice Webinar on Use of Animal-Free Affinity Reagents; Notice of Public Webinar; Registration Information

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) announces a public webinar "Use of Animal-free Affinity Reagents." The webinar is organized on behalf of ICCVAM by the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM). Interested persons may participate via WebEx. Time will be allotted for questions from the audience. Information about the webinar and registration are available at <https://ntp.niehs.nih.gov/go/commprac-2020>.

DATES:

Webinar: January 21, 2020, 11:00 a.m. to approximately 12:30 p.m. EST.

Registration for Webinar: December 9, 2019, until 12:30 p.m. EST January 21, 2020.

Registration to view the webinar is required.

ADDRESSES: Webinar web page <https://ntp.niehs.nih.gov/go/commprac-2020>.

FOR FURTHER INFORMATION CONTACT: Dr. Warren Casey, Director, NICEATM, Division of NTP, NIEHS, P.O. Box 12233, K2-17, Research Triangle Park, NC 27709. Phone: 984-287-3118, Email: warren.casey@nih.gov. Hand Deliver/Courier address: 530 Davis Drive, Room K2021, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background: ICCVAM promotes the development and validation of toxicity testing methods that protect human health and the environment while replacing, reducing, or refining animal use. ICCVAM also provides guidance to test method developers and facilitates collaborations that promote the development of new test methods. To address these goals, ICCVAM will hold a Communities of Practice webinar on "Use of Animal-free Affinity Reagents."

Affinity reagents such as antibodies are used in a range of research, diagnostic, and regulatory applications. However, traditional methods for producing such reagents require immunization of laboratory animals. Therefore, even when applied to nonanimal test methods, their use is inconsistent with the spirit of replacing, reducing, or refining animal use. Use of animal-based affinity reagents also introduces variability into the methods that use them.

This webinar will present a review of the usefulness and limitations of nonanimal-derived affinity reagents and their potential to replace animal-derived reagents. The preliminary agenda and additional information about presentations will be posted at <https://ntp.niehs.nih.gov/go/commprac-2020> as available.

Webinar and Registration: This webinar is open to the public with time scheduled for questions by participants following each presentation. Registration for the webinar is required and is open through 12:30 p.m. EST on January 21, 2020. Registration is available at <https://ntp.niehs.nih.gov/go/commprac-2020>. Interested individuals are encouraged to visit this web page to stay abreast of the most current webinar information. Registrants will receive instructions on how to access and participate in the webinar in the email confirming their registration.

Individuals with disabilities who need accommodation to participate in this event should contact Elizabeth

Mauill at phone: (984) 287-3157 or email: mauill@niehs.nih.gov. TTY users should contact the Federal TTY Relay Service at (800) 877-8339. Requests should be made at least five business days in advance of the event.

Background Information on ICCVAM and NICEATM: ICCVAM is an interagency committee composed of representatives from 16 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. 285I-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. Additional information about ICCVAM can be found at <https://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 test methods and strategies for validation studies and technical evaluations. Additional information about NICEATM can be found at <https://ntp.niehs.nih.gov/go/niceatm>.

Dated: November 18, 2019.

Brian R. Berridge,

Associate Director, National Toxicology Program.

[FR Doc. 2019-25667 Filed 11-25-19; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 Allergy and Infectious Diseases Special Emphasis Panel; HIV/AIDS Maternal, Adolescent and Pediatric Therapeutics Clinical Trials Network Leadership and Operations Center (UM1—Clinical Trial Required).

Date: December 18, 2019.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Roberta Binder, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G21A, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892-9823, (240) 669-5050, rbinder@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 21, 2019.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-25684 Filed 11-25-19; 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 Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as