Wednesday, September 19, 2018 will be presented to the working group prior to the workshop. Any written comments received after the 5:00 p.m. ET, Wednesday, September 19, 2018 deadline through Tuesday, September 25, 2018 will be provided to the working group either before or after the meeting, depending on the volume of comments received and the time required to process them in accordance with privacy regulations and other applicable Federal policies. All written public comments and oral public comment statements received by the deadlines for both oral and written public comments will be provided to the IACC for their consideration and will become part of the public record. Attachments of copyrighted publications are not permitted, but web links or citations for any copyrighted works cited may be provided.

In the 2009 IACC Strategic Plan, the IACC listed the ''Spirit of Collaboration'' as one of its core values, stating that, ''We will treat others with respect, listen to diverse views with open minds, discuss submitted public comments, and foster discussions where participants can comfortably offer opposing opinions.'' In keeping with this core value, the IACC and the NIMH Office of Autism Research Coordination (OARC) ask that members of the public who provide public comments or participate in meetings of the IACC also seek to treat others with respect and consideration in their communications and actions, even when discussing issues of genuine concern or disagreement.

Remote Access: The meeting will be open to the public through a conference call phone number and webcast live on the internet. Members of the public who participate using the conference call phone number will be able to listen to the meeting but will not be heard. If you experience any technical problems with the webcast or conference call, please send an e- mail to *IACCPublicInquiries@mail.nih.gov.* Individuals wishing to participate in person or by using these electronic services and who need special assistance, such as captioning of the conference call or other reasonable accommodations, should submit a request to the Contact Person listed on this notice at least 5 days prior to the meeting.

Special Accommodations: Individuals who participate in person or by using these electronic services and who need special assistance, such as captioning of the conference call or other reasonable accommodations, should submit a request to the Contact Person listed on this notice at least 5 days prior to the meeting.

Security: Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit. Also, as a part of security procedures, attendees should be prepared to present a photo ID at the meeting registration desk during the check-in process. Pre-registration is recommended. Seating will be limited to the room capacity and seats will be on a first come, first serve basis, with expedited check-in for those who are pre-registered.

Meeting schedule subject to change. Information about the IACC is available on the website: *http://www.iacc.hhs.gov.*

Dated: August 1, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–16793 Filed 8–6–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 on Aging Initial Review Group, Biological Aging Review Committee NIA–B.

Date: September 27–28, 2018.

Time: 2:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Rd., Bethesda, MD 20814 (Telephone Conference Call).

Contact Person: Bita Nakhai, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Bldg., 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20814, 301–402–7701, *nakhaib@nia.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: August 1, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–16788 Filed 8–6–18; 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: Vince Contreras, Ph.D., 240–669–2823; *vince.contreras@nih.gov.* Licensing information and copies of the U.S. patent application 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.

Substitutions-Modified Prefusion RSV F Proteins and Their Use

Description of Technology: The respiratory syncytial virus (RSV) fusion (F) glycoprotein is the primary target of neutralizing antibodies. The F glycoprotein exists in at least two conformations, a meta-stable prefusion state, and an extremely stable postfusion state. Both states share several epitopes targeted by neutralizing antibodies, but it has been demonstrated that the prefusion conformation of F contains at least one epitope not present in the postfusion conformation. Natural infection results in neutralizing antibodies that are primarily directed against the prefusion conformation of F, not its postfusion conformation. The instability of the prefusion form of F has

hindered both its characterization and its use as a vaccine antigen.

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases have overcome technical obstacles to produce a homogeneous, soluble RSV F glycoprotein vaccine which is stabilized in the prefusion conformation and has improved stability and immunogenicity compared to the native protein. Additionally, several modifications were introduced to remove the requirement for furin during production, resulting in an increase in expression levels of the immunogen. Stability of the immunogen was increased 20-fold as compared to DS–CAV1 (a prefusion-stabilized RSV F glycoprotein vaccine candidate that is currently being assessed in clinical trials) upon incubation at 60 °C. In mice, these immunogens elicited neutralization titers that were 2 to 5-fold higher than DS–CAV1.

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:* RSV vaccine for human use.
- *Probe:* B cell-sorting probe to isolate potent neutralizing monoclonal antibodies.
- *Diagnostics:* To assess the titer of prefusion-specific antibodies in sera.

Competitive Advantages:

- Increased stability compared to the current leading RSV vaccine candidate (DS-Cav1).
- Elicits increased neutralization titers in mice.

Development Stage:

- *In vivo* testing (mice).

Inventors: Peter D. Kwong (NIAID), M. Gordon Joyce (NIAID), Baoshan Zhang (NIAID), Man Chen (NIAID), Barney S. Graham (NIAID), John R. Mascola (NIAID), Aliaksandr A. Druz (NIAID), Wing-Pui Kong (NIAID), Ivelin Georgiev (NIAID), Yaroslav Tsybovsky (Leidos Biomedical Research), Paul V. Thomas (NIAID), Marie L. Pancera (NIAID), Mallika Sastry (NIAID), Cinque Soto (NIAID), Guillaume B.E. Stewart-Jones (NIAID), Yongping Yang (NIAID), Li Ou (NIAID), Ulrich Baxa (NCI), Emily Rundlet (NIAID), Joseph Van Galen (NIAID).

Publications: Joyce, M. Gordon, *et al.*, Nature structural & molecular biology, 23.9 (2016): 811; PMID: 27478931.

Intellectual Property: HHS Reference Number E–064–2016: U.S. Patent Application No. 62/314,946 filed 03/29/2016; PCT Application Number PCT/US2017/024714 filed 03/29/2017 (pending).

Related Intellectual Property: HHS Reference Number E–081–2013.

Licensing Contact: Vince Contreras, Ph.D., 240–669–2823; *vince.contreras@nih.gov.*

Dated: July 20, 2018.

Suzanne M. Frisbie,

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

[FR Doc. 2018–16835 Filed 8–6–18; 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: 2016–2017; Availability of Report

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

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: 2016–2017. This report, prepared in accordance with requirements of the ICCVAM Authorization Act of 2000, describes activities and accomplishments from January 2016 through December 2017.

ADDRESSES: The report is available at *http://ntp.niehs.nih.gov/iccvamreport/2017/index.html.*

FOR FURTHER INFORMATION CONTACT: Dr. Warren Casey, Director, NICEATM; email: *warren.casey@nih.gov*; telephone: (984) 287–3118.

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 biennial progress report describing ICCVAM activities and accomplishments from January 2016 through December 2017 is now available.

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

- Development of a strategic roadmap for incorporating new approaches into safety testing of chemicals and medical products in the United States.
- Publication of two guidance documents by the U.S. Environmental Protection Agency (EPA) in 2016. One included a policy statement to waive all acute dermal lethality studies for pesticide formulations. The other described a transparent, stepwise process for evaluating and implementing alternative methods for six-pack studies, which test for acute systemic toxicity by the oral, dermal, and inhalation routes; skin and eye irritation; and skin sensitization.
- Publication of notices permitting removal of back-titration hamsters for potency testing of vaccines containing *Leptospira pomona* and *Leptospira grippotyphosa* by the U.S. Department of Agriculture, further reducing the number of hamsters required for leptospirosis vaccine potency testing.
- Publication by the U.S. Food and Drug Administration of the Predictive Toxicology Roadmap for integrating predictive toxicology methods into safety and risk assessments.
- Development by NICEATM and EPA scientists of a defined approach that combines data from 11 high-throughput screening assays with a computational model to identify chemicals with the potential to interact with the androgen receptor pathway.
- Development by NICEATM and ICCVAM scientists of a defined approach that uses non-animal approaches to predict murine local lymph node assay outcomes and human skin sensitization hazard and potency.
- Submission of a proposal to develop a performance-based test guideline for defined approaches to skin sensitization testing and assessment to the Organisation for Economic Co-operation and Development (OECD) by partners in the International Cooperation on Alternative Test Methods in 2016. The proposal was approved as part of the OECD workplan in 2017.
- Launch of the Integrated Chemical Environment, a publicly accessible online resource developed to provide high-quality curated data and