

establish legally enforceable responsibilities. See 21 CFR 10.115(d).

## II. Paperwork Reduction Act of 1995

This guidance contains no collection of information. As discussed in the guidance, FDA intends to develop individual guidances to specify the electronic formats for certain submissions under section 745A(a) of the FD&C Act. We will discuss any information collection subject to clearance by OMB under the Paperwork Reduction Act in each **Federal Register** notice announcing the availability of the individual guidances that specify the required electronic formats.

## III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

## IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>,

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.regulations.gov>.

Dated: December 12, 2014.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2014-29609 Filed 12-17-14; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Complementary & Alternative Medicine; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council for Complementary and Alternative Medicine.

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 Council for Complementary and Alternative Medicine

*Date:* February 6, 2015.

*Closed:* 8:30 a.m. to 9:45 a.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Building 31, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

*Open:* 10:00 a.m. to 4:00 p.m.

*Agenda:* Report from the Institute Director and other staff.

*Place:* National Institutes of Health, Building 31, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

*Contact Person:* Martin H. Goldrosen, Ph.D., Director, Division of Extramural Activities, National Center for Complementary and Alternative Medicine, NIH, 6707 Democracy Blvd., Ste. 401, Bethesda, MD 20892-5475, (301) 594-2014, [goldrosen@mail.nih.gov](mailto:goldrosen@mail.nih.gov).

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. 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.

Information is also available on the Institute's/Center's home page: [nccam.nih.gov/about/naccam/](http://nccam.nih.gov/about/naccam/), where an agenda and any additional information for the meeting will be posted when available. (Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: December 12, 2014.

**Michelle Trout,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2014-29571 Filed 12-17-14; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Eunice Kennedy Shriver National Institute of Child Health & Human Development (NICHD); Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Child Health and Human Development Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. A portion of this 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 for the review and discussion of grant applications. 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.

*Name of Committee:* National Advisory Child Health and Human Development Council.

*Date:* January 22, 2015.

*Open:* January 22, 2015, 8:00 a.m. to 12:10 p.m.

*Agenda:* Report of the Director, NICHD; Report of the Acting Director, Division of Extramural Research, NICHD; Discussion of the Outstanding Investigator Award (R35); and New Business of the Council.

*Closed:* January 22, 2015, 1:15 p.m. to Adjournment.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Building 31, Center Drive, C-Wing, Conference Room 6, Bethesda, MD 20892.

*Contact Person:* Caroline Signore, MD., M.P.H., Acting Director, Division of Extramural Research, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 4A05, MSC 7510, Bethesda, MD 20892, (301) 496-5577.

Any interested person may file written comments with the committee by forwarding the statement to the contact person listed on this notice. The statement should include the name, address, telephone number, and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance

onto the NIH campus. All visitor vehicles, including taxis, hotel, and airport shuttles, will be inspected before being allowed on campus. 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.

In order to facilitate public attendance at the open session of Council in the main meeting room, Conference Room 6, please contact Ms. Lisa Kaeser, Program and Public Liaison Office, NICHD, at 301-496-0536 to make your reservation, additional seating will be available in the meeting overflow rooms, Conference Rooms 7 and 8. Individuals will also be able to view the meeting via NIH Videocast. Please go to the following link for Videocast access instructions at: <http://www.nichd.nih.gov/about/advisory/nachhd/Pages/virtual-meeting.aspx>.

(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: December 12, 2014.

**Michelle Trout,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2014-29570 Filed 12-17-14; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Advisory Committee to the Deputy Director for Intramural Research, National Institutes of Health.

The meeting will be open to the public, 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.

*Name of Committee:* Advisory Committee to the Deputy Director for Intramural Research, National Institutes of Health.

*Date:* January 9, 2015.

*Time:* 1:30 p.m. to 3:00 p.m.

*Agenda:* To discuss the Advisory Committee to the Deputy Director for Intramural Research Report recommendations on the site visit review of the Office of Animal Care and Use.

*Place:* National Institutes of Health, Building 1, Room 160, Tele: 866-556-1098,

Code 48960, 8600 Rockville Pike, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Michael M. Gottesman, Deputy Director, National Institutes of Health, Building One, Room 160, Bethesda, MD 20892, 301-496-1921.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: December 12, 2014.

**Anna Snouffer,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2014-29573 Filed 12-17-14; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of Exclusive License: Multivalent Vaccines for Rabies Virus and Ebola and Marburg (Filoviruses)

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209 and 37 CFR 404, that the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of an exclusive license to practice the following invention as embodied in the following patent applications: E-032-2011/0, Blaney et al., "Multivalent Vaccines for Rabies Virus and Filoviruses", U.S. Patent Application Number 61/439,046, filed on February 3, 2011, PCT Application Number PCT/US2012/23575, filed on February 2, 2012, U.S. Patent Application Number 13/983,545, filed on August 2, 2013, European Patent Application Number 12702953.6, filed on February 2, 2012, and Canadian Patent Application Number 2826594, filed on February 2, 2012, to Exsell BIO, Inc., having a place of business in Shoreview, Minnesota, United States of America. The patent rights in these

inventions have been assigned to the United States of America and Thomas Jefferson University.

**DATES:** Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before January 20, 2015 will be considered.

**ADDRESSES:** Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Peter Soukas, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Email: [ps193c@nih.gov](mailto:ps193c@nih.gov); Telephone: (301) 435-4646; Facsimile: (301) 402-0220.

**SUPPLEMENTARY INFORMATION:** The inventors have developed a new platform based on live or chemically inactivated (killed) rabies virus (RABV) virions containing EBOV glycoprotein (GP) in their envelope. In preclinical trials, immunization with such recombinant RABV virions provided excellent protection in mice against lethal challenge with the mouse adapted EBOV and RABV. More specifically, the inventors have developed a trivalent filovirus vaccine based on killed rabies virus virions for use in humans to confer protection from all medically relevant filoviruses and RABV. Two additional vectors containing EBOV Sudan GP or MARV GP are planned to be constructed in addition to the previously developed EBOV Zaire GP containing vaccine. Live attenuated vaccines have been developed for use in at risk nonhuman primate populations in Africa and inactivated vaccines have been developed for use in humans. One recent use contemplated by the inventors is use of the vaccine candidates to generate polyclonal sera against Filoviruses (*i.e.* Ebola and Marburg).

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404. The prospective exclusive license may be granted unless, within thirty (30) days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.

These patent rights are the subject of a previous **Federal Register** notice (see 79 FR 18039, Monday, March 31, 2014).

The fields of use may be limited to production of polyclonal antibodies for prevention/treatment of Filoviruses in humans and non-human animals.