In 2015 the ICH was reformed to make the ICH a true global initiative that expands beyond the previous ICH a true global initiative that expands beyond the previous ICH international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory Agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the ICH regions over the past two decades. The current ICH process and structure can be found at the following Web site: http://www.ich.org. (FDA has verified the Web site addresses as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.)

II. Webinar Attendance and Participation

A. Registration

If you wish to attend the meeting, please register at the following Web site: https://ich_regional_consultation.eventbrite.com. Registrations may be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, the number of participants from each organization may be limited based on space limitations. Registrants will receive confirmation once they have been accepted. If you need special accommodations because of a disability, please contact Amanda Roache (see FOR FURTHER INFORMATION CONTACT) at least 7 days before the meeting.

B. Requests for Oral Presentations

Interested persons may present data, information, or views orally and/or in writing by registering at the public meeting. Public oral presentations will be scheduled between approximately 1:30 p.m. and 2 p.m. Time allotted for oral presentations may be limited to 5 minutes. Those desiring to make oral presentations should notify Amanda Roache (see FOR FURTHER INFORMATION CONTACT) by April 19, 2017, and submit a brief statement of the general nature of the evidence or arguments they wish to present; the names and addresses, telephone number, fax, and email of proposed participants; and an indication of the approximate time requested to make their presentation. The agenda for the public Webinar will be made available on the Internet at http://www.fda.gov/Drugs/NewsEvents/ucm538015.htm.


Leslie Kux, Associate Commissioner for Policy.

[FR Doc. 2017–04839 Filed 3–10–17; 8:45 am]

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; AREA: Immunology.

Date: March 9, 2017.

Time: 12:00 p.m. to 4:00 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: Alok Mulky, Ph.D., Scientific Review Officer, Center for Scientific Review (CSR), National Institutes of Health (NIH), 6701 Rockledge Dr, Room 4203, Bethesda, MD 20892, (301) 435–3566, alok.mulky@nih.gov

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Neuropharmacology.

Date: March 28, 2017.

Time: 2:00 p.m. to 5:30 p.m.
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: Licensing information and copies of the patent applications 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:

N6, A Novel, Broad, Highly Potent HIV-Specific Antibody

Description of Technology

The N6 antibody has evolved a unique mode of binding that depends less on a variable area of the HIV envelope known as the V5 region and focuses more on conserved regions, which change relatively little among HIV strains. This allows N6 to tolerate changes in the HIV envelope, including the attachment of sugars in the V5 region, a major mechanism by which HIV develops resistance to other VRC01-class antibodies. N6 was shown in pre-clinical studies to neutralize approximately 98 percent of HIV isolates tested. The studies also demonstrate that N6 neutralizes approximately 80 percent of HIV isolates which were resistant to other antibodies of the same class, and does so very potently. Its breadth and potency makes N6 a highly desirable candidate for development in therapeutic or prophylactic strategies.

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

• HIV therapeutic
• HIV prophylactic

Competitive Advantages

• Neutralized 98 percent of HIV isolates tested.
• Neutralized 80 percent of HIV isolates which were resistant to other antibodies of the same class, and does so very potently.

Development Stage: Pre-Clinical.

Inventors: Mark Connors, Jinghe Huang, Byong Ha Kang, John Mascola, Elise Ishida, Tongqing Zhou, Peter Kwong, Anqi Zheng, all of NIAID.


Licensing Contact: Chris Kornak, 240–627–3705, chris.kornak@nih.gov.

Collaborative Research Opportunity: The Technology Transfer and Intellectual Property Office (TTIPO) is seeking parties interested in collaborative research to further co-develop this technology. For collaboration opportunities, please contact Chris Kornak, 240–627–3705, chris.kornak@nih.gov.


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

[FR Doc. 2017–04834 Filed 3–10–17; 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 (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 Allergy and Infectious Diseases Special Emphasis Panel NIAID; Investigator Initiated Program Project Applications (P01).

Date: March 29, 2017.

Time: 11:00 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.