recommendations for testing donations of Whole Blood and blood components for WNV using an FDA-licensed donor screening assay. The recommendations in section III of the guidance apply to all donations of Whole Blood (as defined in 21 CFR 640.1) and blood components for transfusion.

In the **Federal Register** of April 28, 2008 (73 FR 22958), FDA announced the availability of the draft guidance "Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion and Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)," dated April 2008. The draft guidance provided recommendations for testing donations of Whole Blood and blood components and HCT/P donor specimens for WNV using an FDA-licensed donor screening assay. FDA requested that comments on this draft guidance be submitted within 90 days of publication. The 90-day comment period ended on July 28, 2008. In addition, in the **Federal Register** of July 7, 2008 (73 FR 38460), FDA requested the submission of data from the 2008 WNV season relating to the criteria for converting from minipool NAT (MP–NAT) to individual donation NAT (ID–NAT) by January 31, 2009, and stated that we did not intend to finalize the proposed recommendations on conversion from MP–NAT to ID–NAT until we had obtained the additional data. At this time, there is insufficient data to recommend uniform threshold criteria for switching from MP–NAT screening to ID–NAT screening. Until we have sufficient data to support the development of suitable uniform threshold criteria, we consider it appropriate for each blood establishment to define its own threshold criteria for switching from MP–NAT to ID–NAT screening and for reverting to MP–NAT screening.

Additionally, at this time, FDA is continuing to review public comment on our recommendations for testing HCT/P donor specimens for WNV. We believe additional public discussion is warranted. Therefore, we are not finalizing our recommendations for HCT/Ps in this guidance. We intend to seek additional public input and to issue guidance for testing HCT/P donor specimens for WNV in the future.

FDA received numerous comments on the draft guidance and those comments were considered in finalizing the guidance. A summary of changes follows. The guidance announced in this notice: (1) Finalizes only the recommendations as to testing donations of Whole Blood and blood components intended for transfusion for WNV; (2) allows establishments that collect Whole Blood and blood components intended for transfusion flexibility to define their own threshold criteria for switching from MP–NAT to ID–NAT screening; (3) recommends that establishments that collect Whole Blood and blood components intended for transfusion switch from MP–NAT to ID–NAT screening as soon as feasible with 48 hours of reaching the threshold, instead of 24 hours; (4) recommends that establishments notify a blood donor of his or her deferral and counsel the donor following an ID–NAT reactive donation, rather than after additional testing on the reactive index donation; and (5) removes Table 2 (Recommendations on Additional Testing of Blood and Blood Components).

The guidance is being issued in conformance with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 606.100 have been approved under OMB control number 0910–0116; the collections of information in 21 CFR 606.122 have been approved under OMB control number 0910–0116; and the collections of information in 21 CFR 630.6 have been approved under OMB control number 0910–0116.

III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: November 3, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–26870 Filed 11–6–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities, Office of Science Policy, Office of the Director; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the meeting of the National Science Advisory Board for Biosecurity (NSABB).

Name of Committee: National Science Advisory Board for Biosecurity.

Date: December 3, 2009.

Time: 8:30 a.m. to 4 p.m. (Times are approximate and subject to change).

Agenda: Presentations and discussions regarding: (1) Introduction of new NSABB voting members; (2) federal responses to NSABB reports; (3) activities of the Working Groups on Outreach and Education and on International Engagement; (4) synthetic biology and NSABB draft report on biosecurity issues raised by synthetic biology; (5) public comments; and (6) other business of the Board.

Place: Bethesda Marriott, 5151 Pooks Hill Rd., Bethesda, MD 20814.

Contact Person: Ronna Hill, NSABB Program Assistant, NIH Office of Biotechnology Activities, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892, (301) 496–9838.

Under authority 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established the NSABB to provide advice, guidance and leadership regarding federal oversight of dual use research, defined as biological research that generates information and technologies that could be misused to pose a biological threat to public health and/or national security.

The meeting will be open to the public, however pre-registration is strongly recommended due to space limitations.

Persons planning to attend should register online at: *http://oba.od.nih.gov/biosecurity/biosecurity_meetings.html* or by calling the Dixon Group (Contact: Marianne Tshihamba at (202) 281–2800). Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should indicate these requirements upon registration.

This meeting will also be Webcast. To access the Webcast, as well as the draft meeting agenda and pre-registration information, connect to: *http://oba.od.nih.gov/biosecurity/biosecurity_meetings.html.* Please check this site for updates.

Any member of the public interested in presenting oral comments at the meeting may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of an organization may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee. All written comments must be received by November 24, 2009 and should be sent via e-mail to *nsabb@od.nih.gov* with "NSABB Public Comment" as the subject line or by regular mail to 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, Attention Ronna Hill. The statement should include the name, address, telephone number and, when applicable, the business or professional affiliation of the interested person.

Dated: November 3, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–26933 Filed 11–6–09; 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 individualsassociated 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, Nature's Solutions.

Date: December 1, 2009.

Time: 2 p.m. to 4 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: Anshumali Chaudhari, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4124, MSC 7802, Bethesda, MD 20892. (301) 435–1210. *chaudhaa@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Developmental Pharmacology.

Date: December 15–16, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Janet M. Larkin, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1102, MSC 7840, Bethesda, MD 20892. 310–435–1026. *larkinja@csr.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: November 2, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–26925 Filed 11–6–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Acute Kidney Injury Ancillary Studies.

Date: December 4, 2009.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Carol J. Goter-Robinson, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 748, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7791, *goterrobinsonc@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: November 3, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–26931 Filed 11–6–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Prospective Granting of an Exclusive License

AGENCY: Technology Transfer Office, Centers for Disease Control and Prevention (CDC), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This is a notice in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i) that the Technology Transfer Office, Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS), is contemplating the granting of an exclusive worldwide license to practice the invention embodied in the patent application referred to below to International Rollforms, Inc., having a place of business in Deptford, New Jersey. CDC intends to grant rights to practice this invention to no other licensees. The patent rights in this invention have been assigned to the government of the United States of America. The patent to be licensed is:

Title: Instrumented Rock Bolt, Data Logger and User Interface System, CDC Ref. #: I–017–01.

Patent No.: 7,324,007.