FY 2015—Continued

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual hour burden
Volunteers	275	1	30/60	138

FY 2016

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual hour burden
Clinical Center Patients	5000	1	30/60	2500
Family Members of Patients	2000	1	30/60	1000
Visitors to the Clinical Center	500	1	10/60	84
NIH Intramural Collaborators	2000	1	10/60	334
Vendors and Collaborating Commercial Enterprises	500	1	20/60	167
Professionals and Organizations Referring Patients	2000	1	20/60	667
Regulators	30	1	20/60	10
Volunteers	275	1	30/60	138

Dated: October 28. 2013.

David K. Henderson,

Deputy Director for Clinical Care, CC, National Institutes of Health.

[FR Doc. 2013–26610 Filed 11–5–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Science Policy, Office of Biotechnology Activities; Recombinant or Synthetic Nucleic Acid Molecule Research: Action Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)

AGENCY: NIH, Public Health Service, HHS.

ACTION: Notice of Final Action under the *NIH Guidelines.*

SUMMARY: The Office of Biotechnology Activities (OBA) is updating Appendix B (Classification of Human Etiologic Agents on the Basis of Hazard) of the *NIH Guidelines* by specifying the risk group (RG) classification for two organisms: Middle East Respiratory Syndrome coronavirus (MERS-CoV) and *Pseudomonas aeruginosa.*

Background: The *NIH Guidelines* provide guidance to investigators and local Institutional Biosafety Committees (IBCs) for setting containment for research involving recombinant or synthetic nucleic acid molecules. Section II–A, Risk Assessment, instructs investigators and IBCs to make an initial risk assessment based on the RG of the agent that will be manipulated (see Appendix B, Classification of Human Etiologic Agents on the Basis of Hazard). The RG of the agent often correlates with the minimum containment level required for experiments subject to the *NIH Guidelines.* Updating Appendix B by revising the risk groups for certain organisms, or adding new organisms, leads to more uniform containment recommendations that are commensurate with the biosafety risk.

The resulting amendments are ''Minor Actions'' under Section IV–C–1–(b)–2 of the *NIH Guidelines* and, therefore, will be implemented immediately upon publication in the **Federal Register**. However, the OBA welcomes public comment to inform any future changes to Appendix B.

DATES: Comments may be submitted to the OBA in paper or electronic form at the mailing, fax, and email addresses shown below under the heading ''**FOR FURTHER INFORMATION.**'' All comments should be submitted by December 6, 2013. All written comments received in response to this notice will be available for public inspection in the NIH OBA office, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892–7985, weekdays between the hours of 8:30 a.m. and 5:00 p.m.

FOR FURTHER INFORMATION CONTACT: If you have questions, or require additional information about these changes, please contact the OBA by email at *oba@od.nih.gov* or by telephone at 301–496–9838. Comments may be submitted to the same email address or by fax to 301–496–9839 or by mail to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892–7985. Background information may be obtained by contacting the NIH OBA by email at *oba@od.nih.gov.*

Middle East Respiratory Syndrome coronavirus (MERS-CoV)

MERS-CoV is an emerging infectious disease agent that was originally identified in 2012 in Saudi Arabia. The virus is a member of the order Nidovirales, family Coronaviridae, and causes a severe pulmonary syndrome that is similar to what was seen with Severe Acute Respiratory Syndrome coronavirus (SARS-CoV). MERS-CoV has been identified as the cause of a severe respiratory disease in 144 individuals, of which 62 have died (as of October 25, 2013; source: Centers for Disease Control and Prevention (CDC)—*http://www.cdc.gov/coronavirus/mers/*). The overall mortality rate of MERS-CoV infection to date is about four times higher than what was reported for SARS-CoV; although it is of note, in patients over 65 years of age, that mortality from infection with SARS-CoV was reported to exceed 50 percent (based on World Health Organization (WHO) data accessed September 9, 2013, *http://www.who.int/csr/sars/archive/2003_05_07a/en/print.html*). As was the case for SARS-CoV, there are no proven preventive or therapeutic measures against this new virus. In addition, there are many unanswered questions regarding this virus, including questions about how the virus is transmitted. Although the incidence of viral infections caused by MERS-CoV remains highest in, and largely localized to the Arabian Peninsula (138 of 144 cases), the high mortality rate associated with this agent and its epidemic potential has led to close monitoring by the WHO (*http://www.who.int/csr/disease/coronavirus_infections/faq/en/index.html*).

Under Appendix B of the *NIH Guidelines,* most coronaviruses are classified as RG2 viruses. Given the severity of illness seen to date, MERS-CoV will be added to the list of RG3 agents, as was done for SARS-CoV. However, because little is currently known about the source, reservoir, and epidemiology of this virus, the RG classification will be reassessed if new data emerge relevant to the biosafety risks associated with the agent. In addition, while research with RG3 agents is often carried out at Biosafety level 3 containment—with appropriate enhancements depending upon the nature of the agent, e.g., increased respiratory precautions for agents that are transmissible by the aerosol route—the RG of an agent is not the only factor that determines the containment level. As stated in Section II–A of the *NIH Guidelines* (Risk Assessment) ''once the risk group of an agent is identified, this should be followed by a thorough consideration of how the agent is to be manipulated'' and there may be experiments for which a higher containment level is warranted. Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with MERS-CoV are available on the CDC Web site at the following URL: *http://www.cdc.gov/coronavirus/mers/guidelines-lab-biosafety.html.*

Pseudomonas aeruginosa

Bacteria belonging to the genus *Pseudomonas* are ubiquitous in the environment. They are generally considered to be opportunistic pathogens, i.e., able to cause disease in individuals who are immunocompromised. According to the CDC, serious pseudomonas infections usually occur in hospitalized patients and those who are immunocompromised and these infections can lead to severe illness and death (*http://www.cdc.gov/hai/organisms/pseudomonas.html*). Healthy people can also become ill from *Pseudomonas aeruginosa,* especially after exposure to inadequately disinfected water. Per the CDC, ''Ear infections, especially in children, and more generalized skin rashes may occur after exposure to inadequately chlorinated hot tubs or swimming pools. Eye infections have occasionally been reported in persons using extended-wear contact lenses'' (*http://www.cdc.gov/hai/organisms/pseudomonas.html*).

Because this bacterium generally causes mild disease in healthy individuals and there are antibiotics to treat such disease, the OBA will add it to Appendix B as an RG2 bacterium. This is consistent with other assessments of the RG for this pathogen by other biosafety guidances, including the Canadian (*http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/pseudomonas-spp-eng.php*) and the European Community (*http://www.bacterio.net/hazard.html#group2*) guidances.

Appendix B–II–A. Risk Group 2 (RG2)—Bacterial Agents Including Chlamydia.

The following addition will be made to *Appendix B–II–A. Risk Group 2 (RG2)—Bacterial Agents Including Chlamydia:*

Pseudomonas aeruginosa

The following addition will be made to *Appendix B–III–D Risk Group 3 (RG3)—Viruses and Prions:*

Middle East Respiratory Syndrome coronavirus (MERS-CoV)

Dated: October 30, 2013.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health

[FR Doc. 2013–26612 Filed 11–5–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Human Genome Research Institute Special Emphasis Panel, October 15, 2013, 01:00 p.m. to October 15, 2013, 02:30 p.m., National Human Genome Research Institute, 5635 Fishers Lane, Suite 3055, Rockville, MD 20852 which was published in the **Federal Register** on September 16, 2013, 78 FR 26905.

The October 15, 2013 meeting has been moved to December 5, 2013. The meeting is closed to the public.

Dated: October 31, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–26540 Filed 11–5–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Enabling Bioanalytical and Imaging Technologies Study Section, October 10, 2013, 07:45 a.m. to October 11, 2013, 06:00 p.m., Sheraton Delfina Santa Monica Hotel, 530 West Pico Boulevard, Santa Monica, CA 90405 which was published in the **Federal Register** on September 12, 2013, 78 FR 177 Pg. 56239.

The meeting will be held at the Renaissance Washington Dupont Circle Hotel, 1143 New Hampshire Ave. NW., Washington, DC 20037. The meeting will start December 17, 2013 at 9:30 a.m. and end December 18, 2013 at 7:00 p.m. The meeting is closed to the public.

Dated: October 31, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–26529 Filed 11–5–13; 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; 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 Child Health and Human Development Special Emphasis Panel; Reproductive Center's.

Date: November 7–8, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.