Center for Drug Evaluation and Research, by the Commissioner of Food and Drugs.

Dated: October 30, 2013.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 2013–26491 Filed 11–5–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Customer and Other Partners Satisfaction Surveys

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for the opportunity for public comment on the proposed data collection projects, the National Institutes of Health Clinical Center (CC) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) The quality, utility, and clarity of the information to be collected; and (4) Whether the proposed collection minimizes the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and for Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. David K. Henderson, Deputy Director for Clinical Care, National Institutes of Health Clinical Center, 10 Center Drive, Bldg. 10, Rm. 6–1480, Bethesda, MD 20892 or call non-toll-free number (301) 496–3515 or email your request, including your address to: *dkh@nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: Title: Generic Clearance for Surveys of Customers and Other Partners, 0925–0458, Expiration Date 12/31/2013, Type of Submission: Extension, National Institutes of Health Clinical Center (CC), National Institutes of Health (NIH).

Need and Use of Information Collection: The information collected in these surveys will be used by Clinical Center personnel: (1) To evaluate the perceptions of various Clinical Center customers and other partners of Clinical Center services; (2) to assist with the design of modifications of these services, based on customer input; (3) to develop new services, based on customer need; (4) to evaluate the perceptions of various Clinical Center customers and other partners of implemented service modifications, and (5) for hospital accreditation. These surveys are voluntary and necessary for the proper performance of Clinical Center functions and will almost certainly lead to quality improvement activities that will enhance and/or streamline the Clinical Center's operations. The major mechanisms by which the Clinical Center will request customer input is through surveys and focus groups. The surveys will be tailored specifically to each class of customer and to that class of customer's needs. Surveys will either be collected as written documents, as faxed documents, mailed electronically or collected via the web or by telephone from customers. Information gathered from these surveys of Clinical Center customers and other partners will be presented to, and used directly by, Clinical Center management to enhance the services and operations of our organization.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 4,900.

FY 2014

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

FY 2015

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

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*).