TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Draft guidance on monitoring clinical investigations	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Development of Comprehensive Monitoring Plan	88	1.5	132	4	528
Voluntary Submission of Monitoring Plans to FDA	22	1.5	33	2	66
Total	N/A	N/A	N/A	6	594

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatory Information/default.htm, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm,* or *http://www.regulations.gov.*

Dated: August 23, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–21972 Filed 8–26–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Partner and Customer Satisfaction Surveys

SUMMARY: Under the provisions of Section 3507(a)(l)(D) of the Paperwork Reduction Act of 1995 for the opportunity for public comment on the proposed data collection projects, the Center for Scientific Review (CSR), National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on July 22, 2011 (Vol. 76, No. 141, p. 44020) and allowed 60-days for public comment. There was one public comment received during this time.

The purpose of this notice is to allow 30 days for public comment. The National Institutes of Health may not conduct or sponsor and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Extension of Generic Clearance for Voluntary Partner and Customer Satisfaction Surveys.

Type of Information Collection Request: Extension.

Need and Use of Information Collection: The information collected in these surveys will be used by the Center for Scientific Review management and personnel: (1) To assess the quality of the modified operations and processes now used by CSR to review grant applications; (2) To assess the quality of service provided by CSR to our customers; (3) To enable identification of the most promising biomedical research that will have the greatest impact on improving public health by using a peer review process that is fair unbiased from outside influence, timely, and (4) To develop new modes of operation based on customer need and customer feedback about the efficacy of implemented modifications. These surveys will almost certainly lead to quality improvement activities to enhance and/or streamline CSR's operations. The major mechanism by which CSR will request input is through surveys. The major initiatives ongoing at the present time include: Shortening the review and application process, shortening the grant application, recruiting the best reviewers by developing additional review modes, improving study section alignment to ensure the best reviews, and others. Surveys will be collected via Internet. Information gathered from these surveys will be presented to, and used directly by, CSR management to enhance the operations, processes, organization of, and services provided by the Center.

Frequency of Response: The participants will respond once, unless there is a compelling reason for a subsequent survey. *Affected public:* Universities, not-forprofit institutions, business or other forprofit, small businesses and organizations, and individuals. *Type of Respondents:* Adult scientific professionals.

ESTIMATES OF ANNUALIZED HOUR BURDEN

[Totals rounded off to the nearest hour]

Type of respondent	Number of respondents	Frequency of response	Average time per response (Hr)	Total annual hour burden
Adult scientific professionals (via Mail/Telephone/Internet)	5000	1	0.25	1250
Adult scientific professional (via focus groups)	75	1	1	188
Total	5075	.....	.....	1438

Requests for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the CSR, 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) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond while maintaining their anonymity, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov,* or by fax to 202–395–6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact George Chacko, PhD, Center for Scientific Review, NIH, Room 3030, 6701 Rockledge Drive, Bethesda, MD 20892–7776, or call non-toll-free number 301–435–1133 or E-mail your request, including your address to: *chackoge@csr.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of publication of this notice.

Dated: August 22, 2011.

George Chacko,

Director of Planning, Analysis, and Evaluation, CSR, National Institutes of Health.

[FR Doc. 2011–21980 Filed 8–26–11; 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 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 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 intramural programs and projects and discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the intramural programs and projects, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Child Health and Human Development Council; NACHHD Subcommittee on Planning and Policy.

Date: September 6, 2011.

Closed: 9 a.m. to 10:30 a.m.

Agenda: To review and evaluate the Division of Intramural Research Laboratories site visit reports.

Place: National Institutes of Health, Building 31, 31 Center Drive, Room 31 2A03, Bethesda, MD 20892 (Telephone Conference Call).

Information is also available on the Institute's/Center's home page: *http://www.nichd.nih.gov/about/nachhd.htm*, where an agenda and any additional information for the meeting will be posted when available.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the intramural research review cycle.

(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: August 22, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–21967 Filed 8–26–11; 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 individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group, Somatosensory and Chemosensory Systems Study Section.

Date: October 4–5, 2011.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Westin Alexandria, 400 Courthouse Square, Alexandria, VA 22314.

Contact Person: M Catherine Bennett, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7846, Bethesda, MD 20892, 301–435–1766, *bennettc3@csr.nih.gov.*

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group, Cellular, Molecular and Integrative Reproduction Study Section.

Date: October 4, 2011.

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

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Gary Hunnicutt, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, 301–435–0229, *gary.hunnicutt@nih.gov.*

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group, Oral, Dental and Craniofacial Sciences Study Section.

Date: October 4–5, 2011.

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

Agenda: To review and evaluate grant applications.

Place: Beacon Hotel and Corporate Quarters, 1615 Rhode Island Avenue, NW., Washington, DC 20036.

Contact Person: Yi-Hsin Liu, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301–435–1781, *liuyh@csr.nih.gov.*

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group, Pregnancy and Neonatology Study Section.

Date: October 4, 2011.

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

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency—Baltimore, 300 Light Street, Baltimore, MD 21202.

Contact Person: Michael Knecht, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of