5364/ig/index.cfm?page=775.
9. The FDA Web page for information on Pediatric X-ray Imaging, is available at *http://www.fda.gov/RadiationEmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm298899.htm*.
10. Under section 513(i)(1)(E)(i) of the Federal Food, Drug, and Cosmetic Act, when determining that a device is substantially equivalent to a predicate device, FDA may require limitations in device labeling about off-label use of the device when ''there is a reasonable likelihood'' of such use, and if ''such use could cause harm.'' Such determinations are made on a case by case basis and other requirements must be met, including a consultation between FDA and the 510(k) submitter, before such limitations can be required. FDA's policy on when a device may be found ''substantially equivalent with limitations'' is discussed further in the guidance entitled ''Determination of Intended Use for 510(k) Devices; Guidance for CDRH Staff (Update to K98–1),'' available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm082162.htm,* December 3, 2003.
11. The FDA guidance entitled ''Premarket Assessment of Pediatric Medical Devices,'' is available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089742.pdf,* May 14, 2004.
12. McDowell, M.A., C.D. Fryar, C.L. Ogden, and K. M. Flegal, ''Anthropomorphic Reference Data for Children and Adults: United States, 2003–2006,'' *National Health Statistics Reports,* vol. 10, 1–48, available at *http://www.cdc.gov/nchs/data/nhsr/nhsr010.pdf,* October 22, 2008.
13. National Research Council of the National Academies, Committee to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation, ''Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII Phase,'' *National Academy of Sciences* (National Academies Press), is available at *http://www.nap.edu/openbook.php?isbn=030909156X,* 2006.
14. See 21 CFR 807.92.

Dated: May 4, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–11262 Filed 5–9–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Proposed Information Collection; Request for Public Comment: Indian Health Service Loan Repayment Program (LRP)

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, which requires 30 days for public comment on proposed information collection projects, the Indian Health Service (IHS) 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 project was previously published in the **Federal Register** (77 FR 11558) on February 27, 2012 and allowed 60 days for public comment. No public comment was received in response to the notice. The purpose of this notice is to allow 30 days for public comment to be submitted directly to OMB.

Proposed Collection: Title: 0917–0014, ''Indian Health Service Loan Repayment Program.'' *Type of Information Collection Request:* Revision of currently approved information collection, 0917–0014, ''Indian Health Service Loan Repayment Program.'' The LRP application has been revised so that it is now available in an electronically fillable and fileable format. *Form(s):* The IHS LRP Information Booklet contains the instructions and the application formats. *Need and Use of Information Collection:* The IHS LRP identifies health professionals with pre-existing financial obligations for education expenses that meet program criteria and who are qualified and willing to serve at, often remote, IHS health care facilities. Under the program, eligible health professionals sign a contract through which the IHS agrees to repay part or all of their indebtedness for professional training time in IHS health care facilities. This program is necessary to augment the critically low health professional staff at IHS health care facilities.

Any health professional wishing to have their health education loans repaid may apply to the IHS LRP. A two-year contract obligation is signed by both parties, and the individual agrees to work at an IHS location and provide health services to American Indian and Alaska Native individuals.

The information collected via the on-line application from individuals is analyzed and a score is given to each applicant. This score will determine which applicants will be awarded each fiscal year. The administrative scoring system assigns a score to the geographic location according to vacancy rates for that fiscal year and also considers whether the location is in an isolated area. When an applicant accepts employment at a location, they in turn ''pick-up'' the score of that location. *Affected Public:* Individuals and households. *Type of Respondents:* Individuals.

The table below provides: Types of data collection instruments, Estimated number of respondents, Number of responses per respondent, Annual number of responses, Average burden hour per response, and Total annual burden hour(s).

ESTIMATED BURDEN HOURS

Data collection instrument(s)	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual responses (in hours)
LRP Application	510	1	1.5	765

There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

Requests for Comments: Your comments and/or suggestions are invited on one or more of the following points:

(a) Whether the information collection activity is necessary to carry out an agency function;

(b) Whether the agency processes the information collected in a useful and timely fashion;

(c) The accuracy of public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information);

(d) Whether the methodology and assumptions used to determine the estimates are logical;

(e) Ways to enhance the quality, utility, and clarity of the information being collected; and

(f) How the newly created online application assists the applicant efficiently and effectively.

Direct your comments to OMB: Send your comments and suggestions regarding the proposed information collection contained in this notice, especially regarding the estimated public burden and associated response time to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for IHS.

To request more information on the proposed collection, or to obtain a copy of the data collection instruments and/or instruction(s) contact: Ms. Tamara Clay, IHS Reports Clearance Officer, 801 Thompson Avenue, TMP, Suite 450–30, Rockville, MD 20852–1627; call non-toll free (301) 443–4750; send via facsimile to (301) 443–2316; or send your email requests, comments, and return address to: *Tamara.Clay@ihs.gov. Comment Due Date:* June 11, 2012. Your comments regarding this information collection are best assured of having full effect if received within 30 days of the date of this publication.

Dated: May 4, 2012.

Yvette Roubideaux,

Director, Indian Health Service.

[FR Doc. 2012–11284 Filed 5–9–12; 8:45 am]

BILLING CODE 4165–16–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; Topics in Development, Signaling, and Disease.

Date: May 15, 2012.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Cathy J. Wedeen, Ph.D., Scientific Review Officer, Division of Scientific Review, OD, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01–G, Bethesda, MD 20892, 301–435–6878, *wedeenc@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding 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: May 4, 2012.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–11347 Filed 5–9–12; 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 Congenital Defects Topics.

Date: May 18, 2012.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Cathy J. Wedeen, Ph.D., Scientific Review Officer, Division of Scientific Review, OD, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01–G, Bethesda, MD 20892, 301–435–6878, *wedeenc@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding 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: May 4, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–11332 Filed 5–9–12; 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Integrative Neuroscience.

Date: May 30–31, 2012.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Edwin C Clayton, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5180, MSC 7844, Bethesda, MD 20892, 301–408–9041, *claytone@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Synthetic and Biological Chemistry B Study Section.

Date: May 30–31, 2012.

Time: 8:30 a.m. to 5:00 p.m.