

This level 1 final guidance is being issued in accordance with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on compliance with section 113 of Modernization Act, i.e., submitting information on clinical trials for serious or life-threatening diseases and conditions to a Clinical Trials Data Bank developed by the National Library of Medicine, National Institutes of Health. 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. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written or electronic comments on the guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: March 1, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-6421 Filed 3-15-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Uniform Data System (OMB No. 0915-0193)—Revision

This is a request for a revision of approval of the Uniform Data System (UDS), which contains the annual reporting requirements for the cluster of primary care grantees funded by the Bureau of Primary Health Care (BPHC),

Health Resources and Services Administration (HRSA). The UDS includes reporting requirements for grantees of the following primary care programs: Community Health Centers, Migrant Health Centers, Health Care for the Homeless, Outreach and Primary Health Services for Homeless Children and Public Housing Primary Care, and Healthy Schools Healthy Communities. Authorizing Legislation is found in Public Law 104-299, Health Center Consolidation Act of 1996, enacting Section 330 of the Public Health Service Act.

The Bureau of Primary Health Care collects data on its programs to ensure compliance with legislative mandates and to report to Congress and policymakers on program accomplishments. To meet these objectives, BPHC requires a core set of information collected annually that is appropriate for monitoring and evaluating performance and reporting on annual trends. The UDS includes two components: the Universal Report, completed by all grantees, provides data on services, staffing, and financing; and the Grant Report, completed by grantees funded under the Homeless, Public Housing Program or Health Schools Healthy Communities as well as one of the other programs, provides data on characteristics of users whose services fall within the scope of the Homeless, Public Housing Program, Healthy Schools Healthy Communities grant. Grantees are also asked to provide information on the charges, collections, bad debt write off and contractual disallowances by payor sources (Medicaid, Medicare, self pay and private insurance). In addition, grantees need to include categories to some of the lists (e.g., services, ICD codes, CPT codes) and annotating the forms to indicate which lines are subtotals and the lines to which they sum.

Estimates of annualized reporting burden are as follows:

Type of report	Number of respondents	Hours per response	Total burden hours
Universal Report	757	24	18,168
Grant Report	114	16	1,824
Total	757		19,992

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 11-05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: March 12, 2002.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 02-6422 Filed 3-15-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Internet Tools to Enhance Use of Online Health Resources.

Date: April 18, 2002.

Time: 1 p.m. to 2 p.m.

Agenda: To review and evaluate contract proposals.

Place: Executive Plaza North, Conference Room C, 6130 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call).

Contact Person: Joyce C. Pegues, PhD, Scientific Review Administrator, Special Review and Resources Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 7149, Bethesda, MD 20892. 301/594-1286. (Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: March 11, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02-6384 Filed 3-15-02; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Cancer Communication and Interactive Media Technology.

Date: April 18, 2002.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Executive Plaza North, Conference Room C, 6130 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call).

Contact Person: Joyce C. Pegues, PhD, Scientific Review Administrator, Special Review and Resources Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 7149, Bethesda, MD 20892. 301/594-1286. (Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: March 11, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02-6385 Filed 3-15-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 Cancer Institute Initial Review Group, Subcommittee D—Clinical Studies.

Date: April 25, 2002.

Time: 7 a.m. to 7 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn—Georgetown, 2101 Wisconsin Avenue, NW, Washington, DC 20007.

Contact Person: William D. Merritt, PhD, Scientific Review Administrator, Grants Review Branch, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8129, MSC 8328, Bethesda, MD 20892-8328. 301-496-9767.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: March 11, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02-6386 Filed 3-15-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice