electronically or through manual entry of the device data) for purposes of automatically assessing patient specific data or for providing support in making clinical decisions. FDA plans to address such stand-alone software in a separate guidance. In order to provide a reasonable assurance of the safety and effectiveness of such software, and to ensure consistency between the draft guidance, ''Mobile Medical Applications,'' and the planned guidance on stand-alone software that provides clinical decision support (CDS), FDA is seeking comment on the following issues:

- What factors should FDA consider in determining the risk classification of different types of software that provide CDS functionality? Please provide examples of how those factors would be applied for such software that you believe should be in class I, class II, and class III;
- How should the FDA assess stand-alone software that provides CDS functionality, to assure reasonable safety and effectiveness? For example, to what extent can FDA rely on a manufacturer's demonstration that it has a robust quality system with appropriate quality assurance and design controls? Under what circumstances should the submission of clinical data be required?; and
- Are there specific controls that manufacturers should implement that could change the risk classification or reduce the premarket data requirements for particular types of stand-alone software that provide CDS functionality?

III. Where can I find out more about this public workshop?

Background information on the public workshop, registration information, the agenda, information about lodging, transcripts, and other relevant information will be posted, as it becomes available, on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.*

IV. Will there be transcripts of the meeting?

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

Dated: August 9, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–20574 Filed 8–11–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Web-Based Skills Training for SBIRT (Screening Brief Intervention and Referral to Treatment)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute on Drug Abuse (NIDA), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on May 24, 2011, Vol 76, #100, page 30177–30178, and allowed 60 days for public comment. One request for the draft instruments was received from the public. These were provided to the requestor. The purpose of this notice is to allow an additional 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: Web-based Skills Training for SBIRT (Screening Brief Intervention and Referral to Treatment).

Type of Information Collection Request: NEW.

Need and Use of Information Collection: The project aims to increase the provision of screening, brief intervention, and referral to treatment (SBIRT) for substance use in primary care by developing an engaging, interactive case-based training program that will be delivered over the Internet, providing convenient access to screening and brief intervention skills training and resources for busy PCPs. The goal of this study is to evaluate the effectiveness of this training on provider behavior and/or patient outcome and the program's utility as a training tool in a real-world medical setting. The training is named SBIRT–PC. Study participants will be randomly assigned to complete SBIRT–PC or a control training, consisting of online reading materials. Effectiveness will be evaluated in terms of differential SBIRT-related knowledge, attitudes, self-efficacy, self-reported clinical practices, skills as measured by virtual standardized patient evaluations (VSPE) and a telephone-based standardized patient (SP) interaction. Participants in each condition will also complete a training satisfaction questionnaire.

Frequency of Response: On occasion.

Affected Public: Private sector; businesses or other for-profit.

Type of Respondents: Primary Care Providers.

The annual reporting burden is as follows:

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per set of responses	Estimated total annual burden hours requested
Primary Care Providers	94	1	2.0	188

There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request 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 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) 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, including the use of appropriate 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, contact: Quandra Scudder, Project Officer, National Institute on Drug Abuse NIDA, NIH, 6001 Executive Boulevard, Bethesda, MD 20892–9557, or call non-toll-free number (301) 594–0394 or E-mail your request, including your address to *scudderq@nida.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 this publication.

Dated: August 4, 2011.

Mary Affeldt,

Executive Officer, (OM Director) NIDA.

[FR Doc. 2011–20542 Filed 8–11–11; 8:45 am]

BILLING CODE 4140–01–P

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. 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 Cancer Institute Initial Review Group; Subcommittee G—Education.

Date: September 20–21, 2011.

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

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Jeannette F. Korczak, PhD, Scientific Review Administrator, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd., Room 8115, Bethesda, MD 20892, 301–496–9767, *korczakj@mail.nih.gov*.

(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: August 8, 2011.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–20536 Filed 8–11–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences Notice of Meetings

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of meetings of the Interagency Breast Cancer and Environmental Research Coordinating Committee.

The meetings will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Interagency Breast Cancer and Environmental Research Coordinating Committee.

Date: October 12, 2011.

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

Agenda: The purpose of the meeting is to continue the work of the Research Process Subcommittee as it addresses a broad set of objectives related to the overall mandate of the IBCERC. The meeting agenda will be available on the Web at *http://www.niehs.nih.gov/about/orgstructure/boards/ibcercc/*.

Place: NIEHS/National Institutes of Health, Building 4401, East Campus, 79 T.W. Alexander Drive, Research Triangle Park, NC 27709 (Telephone Conference Call).

To attend the meeting, please RSVP via e-mail to *ibcercc@niehs.nih.gov* at least 10 days in advance and instructions for joining the meeting will be provided.

Contact Person: Gwen W. Collman, PhD, Director, Division of Extramural Research and Training (DERT), Nat. Inst. of Environmental Health Sciences, National Institutes of Health, 615 Davis Dr., KEY615/3112, Research Triangle Park, NC 27709, (919) 541–4980, *collman@niehs.nih.gov.*

Name of Committee: Interagency Breast Cancer and Environmental Research Coordinating Committee.

Date: October 26, 2011.

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

Agenda: The purpose of the meeting is to continue the work of the Research Process Subcommittee as it addresses a broad set of objectives related to the overall mandate of the IBCERC. The meeting agenda will be available on the Web at *http://www.niehs.nih.gov/about/orgstructure/boards/ibcercc/*.

To attend the meeting, please RSVP via e-mail to *ibcercc@niehs.nih.gov* at least 10 days in advance and instructions for joining the meeting will be provided.

Place: NIEHS/National Institutes of Health, Building 4401, East Campus, 79 T.W. Alexander Drive, Research Triangle Park, NC 27709 (Telephone Conference Call).

Contact Person: Gwen W. Collman, PhD, Director, Division of Extramural Research and Training (DERT), Nat. Inst. of Environmental Health Sciences, National Institutes of Health, 615 Davis Dr., KEY615/3112, Research Triangle Park, NC 27709, (919) 541–4980, *collman@niehs.nih.gov.*

Name of Committee: Interagency Breast Cancer and Environmental Research Coordinating Committee.

Date: November 10, 2011.

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

Agenda: The purpose of the meeting is to continue the work of the Research Process Subcommittee as it addresses a broad set of objectives related to the overall mandate of the IBCERC. The meeting agenda will be available on the Web at *http://www.niehs.nih.gov/about/orgstructure/boards/ibcercc/*.

Place: NIEHS/National Institutes of Health, Building 4401, East Campus, 79 T.W. Alexander Drive, Research Triangle Park, NC 27709 (Telephone Conference Call).

To attend the meeting, please RSVP via e-mail to *ibcercc@niehs.nih.gov* at least 10 days in advance and instructions for joining the meeting will be provided.

Contact Person: Gwen W. Collman, PhD, Director, Division of Extramural Research and Training (DERT), Nat. Inst. of Environmental Health Sciences, National Institutes of Health, 615 Davis Dr., KEY615/3112, Research Triangle Park, NC 27709, (919) 541–4980, *collman@niehs.nih.gov.*

Any member of the public interested in presenting oral comments to the committee should submit their remarks in writing at least 10 days in advance of the meeting. Comments in document format (*i.e.* WORD, Rich Text, PDF) may be submitted via e-mail to *ibcercc@niehs.nih.gov* or mailed to the