

of the grant be given a copy of the statement required by paragraph (a);

(d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will—

(1) Abide by the terms of the statement; and

(2) Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction;

(e) Notifying the agency in writing, within 10 calendar days after receiving notice under paragraph (d)(2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to every grant officer or other designee on whose grant activity the convicted employee was working, unless the Federal agency has designated a central point for the receipt of such notices. Notice shall include the identification number(s) of each affected grant;

(f) Taking one of the following actions, within 30 calendar days of receiving notice under paragraph (d)(2), with respect to any employee who is so convicted—

(1) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or

(2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

(g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e) and (f).

(B) The grantee may insert in the space provided below the site(s) for the performance of work done in connection with the specific grant:

Place of Performance (Street address, city, county, state, zip code):

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Check if there are workplaces on file that are not identified here.

*Alternate II. (Grantees Who Are Individuals)*

(a) The grantee certifies that, as a condition of the grant, he or she will not engage in the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance in conducting any activity with the grant;

(b) If convicted of a criminal drug offense resulting from a violation occurring during the conduct of any grant activity, he or she will report the conviction, in writing, within 10 calendar days of the conviction, to every grant officer or other designee, unless the Federal agency designates a central point for the receipt of such notices. When notice is made to such a central point, it shall include the identification number(s) of each affected grant.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Industry Exchange Workshop on Food and Drug Administration Clinical Trial Requirements; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA), Baltimore District, in cooperation with the Society of Clinical Research Associates (SoCRA), is announcing a workshop on FDA clinical trial statutory and regulatory requirements. This 2-day workshop for the clinical research community targets sponsors, monitors, clinical investigators, institutional review boards, and those who interact with them for the purpose of conducting FDA regulated clinical research. The workshop will include both industry and FDA perspectives on proper conduct of clinical trials regulated by FDA.

**Date and Time:** The public workshop is scheduled for Wednesday, May 17, 2006, from 8:30 a.m. to 5 p.m. and Thursday, May 18, 2006, from 8:30 a.m. to 4 p.m.

**Location:** The public workshop will be held at the Radisson Plaza Lord Baltimore, 20 West Baltimore St., Baltimore, MD 21201, 410-539-8400, FAX: 410-625-1060.

**Contact:** Marie Falcone, Food and Drug Administration, U.S. Customhouse, 200 Chestnut St., rm. 900, Philadelphia, PA 19106, 215-717-3703, FAX: 215-597-5798, e-mail: [Marie.Falcone@fda.hhs.gov](mailto:Marie.Falcone@fda.hhs.gov).

**Registration:** Send registration information (including name, title, firm name, address, telephone, and fax number) and the registration fee of \$550 (member), \$625 (nonmember), or \$500 (Government employee nonmember). (The registration fee for nonmembers includes a 1-year membership.) The registration fee for FDA employees is waived. Make the registration fee payable to SoCRA, P.O. Box 101, Furlong, PA 18925. To register via the Internet go to [http://www.socra.org/FDA\\_Conference.htm](http://www.socra.org/FDA_Conference.htm). (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**).

The registrar will also accept payment by major credit cards. For more information on the meeting, or for questions on registration, contact 800-SoCRA92 (800-762-7292), or 215-822-

8644, or e-mail: [socramail@aol.com](mailto:socramail@aol.com). Attendees are responsible for their own accommodations. To make reservations at the Radisson Plaza Lord Baltimore hotel at the reduced conference rate, contact the Radisson Plaza Lord Baltimore hotel (see **LOCATION**) before April 17, 2006. The registration fee will be used to offset the expenses of hosting the conference, including meals, refreshments, meeting rooms, and materials.

Space is limited, therefore interested parties are encouraged to register early. Limited onsite registration may be available. Please arrive early to ensure prompt registration. If you need special accommodations due to a disability, please contact Marie Falcone (see **CONTACT**) at least 7 days in advance of the workshop.

**SUPPLEMENTARY INFORMATION:** The workshop on FDA clinical trials statutory and regulatory requirements helps fulfill the Department of Health and Human Services and FDA's important mission to protect the public health by educating researchers on proper conduct of clinical trials. Topics for discussion at the workshop include the following: (1) FDA regulation of the conduct of clinical research;

(2) Medical device, drug, biological product and food aspects of clinical research;

(3) Investigator initiated research;

(4) Preinvestigational new drug application meetings and FDA meeting process;

(5) Informed consent requirements;

(6) Ethics in subject enrollment;

(7) FDA regulation of institutional review boards;

(8) Electronic records requirements;

(9) Adverse event reporting;

(10) How FDA conducts bioresearch inspections; and

(11) What happens after the FDA inspection.

FDA has made education of the research community a high priority to ensure the quality of clinical data and protect research subjects. The workshop helps to implement the objectives of section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise. The workshop also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121) by providing outreach activities by Government agencies directed to small businesses.

Dated: March 1, 2006.  
**Jeffrey Shuren,**  
*Assistant Commissioner for Policy.*  
 [FR Doc. E6-3229 Filed 3-6-06; 8:45 am]  
**BILLING CODE 4160-01-S**

**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) 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) will publish periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (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, 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

of other forms of information technology.

**Proposed Project: Sentinel Centers Network Technical Assistance Needs Assessment (NEW)**

HRSA's Bureau of Primary Health Care (BPHC) established the Sentinel Centers Network (SCN) to assist in addressing critical quality, programmatic, and policy issues. Health centers submit core data periodically that is extracted from existing information systems. In order to assess needs for technical assistance (TA), information will be requested from centers regarding current information systems, updates/changes to information systems, and other TA needs. This information will be collected periodically via a project Web site and will be used to manage the ongoing needs of network participants.

The burden estimate for this project is as follows:

Form	Number of respondents	Number of responses per respondent	Total responses	Hours per response	Total burden hours
TA Inventory .....	38	4	152	.25	38

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 10-33 Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Written comments should be received with 60 days of this notice.

Dated: March 1, 2006.  
**Tina M. Cheatham,**  
*Director, Division of Policy Review and Coordination.*  
 [FR Doc. E6-3167 Filed 3-6-06; 8:45 am]  
**BILLING CODE 4165-15-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Proposed Collection; Comment Request**

In compliance with 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, Pub. L. 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 at 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: Women's Physical Activity and Eating Tools Assessment: NEW**

The HRSA Office of Women's Health (OWH) developed the Bright Futures for Women's Health and Wellness (BFWHW) Initiative to help expand the scope of women's preventive health activities, particularly related to nutrition and physical activity. Building upon a previous pilot study, an intermediate assessment of the BFWHW health promotion tools and materials related to physical activity and healthy

eating will be conducted in order to identify characteristics of both individual and organizational change toward health and wellness associated with the uptake and use of the BFWHW tools. This data collection effort will ensure that the BFWHW tools are disseminated and utilized in the most effective ways, used to inform future BFWHW programming, and added to the literature regarding evidence-based women's health and wellness initiatives.

Towards this end, questionnaires will be used to collect data from adolescent and adult women clients, providers, and administrators of community health provider organizations. Data collected will include process, impact, and outcome measures. Data domains include the implementation and use of the BFWHW tools, including distribution and use; provider training; organizational characteristics related to successful implementation; client and provider awareness; attitudes about the importance of physical activity, nutrition and self-efficacy to take steps to make effective changes; increase in knowledge and intent to change behavior after exposure; and short-term outcomes related to improved preventive healthcare for women. A total of six organizations, which may include HHS Centers of Excellence and Community Centers of Excellence in