

**Kimberly S. Lane,**

*Deputy Director, Office of Science Integrity,  
Office of the Associate Director for Science,  
Office of the Director, Centers for Disease  
Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Board of Scientific Counselors, Office of Public Health Preparedness and Response (BSC, OPHPR)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

*Times and Dates:*

9:30 a.m.–3 p.m., August 21, 2012; 9:30 a.m.–3 p.m., August 22, 2012.

*Place:* CDC, 1600 Clifton Road NE., Roybal Campus, Building 19, Auditorium B2, Atlanta, Georgia 30329.

*Status:* Open to the public limited only by the space available. The meeting room will accommodate up to 30 people. Public participants should pre-register for the meeting as described in Additional Information for Public Participants.

*Purpose:* This Board is charged with providing advice and guidance to the Secretary, Department of Health and Human Services (HHS), the Assistant Secretary for Health (ASH), the Director, Centers for Disease Control and Prevention (CDC), and the Director, Office of Public Health Preparedness and Response (OPHPR), concerning strategies and goals for the programs and research within OPHPR, monitoring the overall strategic direction and focus of the OPHPR Divisions and Offices, and administration and oversight of peer review of OPHPR scientific programs. For additional information about the Board, please visit: <http://www.cdc.gov/phpr/science/counselors.htm>.

*Matters to be Discussed:* Agenda items for this meeting include: (1) Briefings and BSC deliberation on the following topics: OPHPR International Activities; National Health Security Preparedness Index Update; update on the activities of the joint BSC-National Biodefense Science Board Strategic National Stockpile ad hoc working group; CDC's response to laboratory biosafety issues; Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) and CDC's smallpox vaccine program; OPHPR's national policy initiatives; history and overview of the Preparedness and Emergency Response Learning Centers; update on CDC's biosurveillance and situational awareness activities; (2) BSC liaison representative updates to the Board highlighting organizational activities relevant to the OPHPR mission.

Agenda items are subject to change as priorities dictate.

*Additional Information for Public*

*Participants:* Members of the public that wish to attend this meeting should pre-register by submitting the following information by email, facsimile, or phone (see Contact Person for More Information) no later than 12 noon (EDT) on Monday, August 13, 2012:

- Full Name,
- Organizational Affiliation,
- Complete Mailing Address,
- Citizenship, and
- Phone Number or Email Address.

*Contact Person for More Information:*

Marquita Black, Office of Science and Public Health Practice Executive Assistant, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop D-44, Atlanta, Georgia 30333, telephone (404) 639-7325; facsimile (404) 639-7977; email: [OPHPR.BSC.Questions@cdc.gov](mailto:OPHPR.BSC.Questions@cdc.gov).

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: July 27, 2012.

**Catherine Ramadei,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No.FDA-2012-N-0001]**

#### Statistical Process Controls for Blood Establishments; Public Workshop

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

**ACTION:** Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: "Statistical Process Controls for Blood Establishments." The purpose of this public workshop is to discuss the implementation of statistical process controls to validate and monitor manufacturing processes in blood establishments. The public workshop has been planned in partnership with the AABB, America's Blood Centers, and the Department of Health and Human Services (HHS) Office of the Assistant Secretary for Health. The public workshop will include presentations and discussions led by experts from government and industry.

*Dates and Times:* The public workshop will be held on October 19, 2012, from 8:30 a.m. to 5 p.m.

*Location:* The public workshop will be held at the FDA White Oak Campus, The Great Room, Bldg. 31, 10903 New Hampshire Ave. Silver Spring, MD, 20993. Please visit the following Web site for location, parking, security, and travel information: <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>. The public workshop will also be available to be viewed online via webcast.

*Streaming Webcast of the Public Workshop:* For those unable to attend in person, FDA will webcast the public workshop. To join the web-cast of the public workshop, please go to: <https://collaboration.fda.gov/stat101912/>.

If you have never attended a Connect Pro meeting before: Test your connection: [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). Get a quick overview: [http://www.adobe.com/go/connectpro\\_overview](http://www.adobe.com/go/connectpro_overview).

*Contact Person:* Jennifer Scharpf, Center for Biologics Evaluation and Research (HFM-302), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6128, FAX: 301-827-2843, email: [CBEROBRRWorkshops@fda.hhs.gov](mailto:CBEROBRRWorkshops@fda.hhs.gov).

*Registration:* Mail, fax, or email your registration information (including name, title, firm name, address, telephone and fax numbers, and email address) to Jennifer Scharpf (see *Contact Person*) by September 27, 2012. Please indicate if you will attend the workshop in person or if you will participate in the webcast. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Those who wish to present at the workshop must attend in person. Registration on the day of the public workshop will be provided on a space-available basis beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Jennifer Scharpf (see *Contact Person*) at least 7 days in advance.

*Requests for Oral Presentations:* Interested persons are invited to make presentations relevant to the public workshop topic. Attendees who wish to make presentations at the public workshop should notify the Contact Person and submit a brief statement of the general nature of the presentation before September 27, 2012. Presentations will be scheduled on the afternoon of October 19, 2012. Time allotted for each presentation may be limited depending on the number of individuals requesting to speak.

**SUPPLEMENTARY INFORMATION:** Statistical process control is the application of statistical methods to the monitoring, or quality control, of a manufacturing process. The implementation of acceptable statistical process controls ensures that a process performs predictably to manufacture a product that meets specific standards. FDA monitors manufacturing procedures, validation summaries, and quality control data prior to licensure and during periodic inspection of facilities.

Millions of units of Whole Blood and blood components, including those collected by apheresis, are manufactured in the United States annually. Blood establishments manufacture these products in accordance with specific standards established by FDA regulations and guidance, as well as in accordance with specifications established by device manufacturers and industry standards. To ensure that product standards are met, blood establishments validate manufacturing processes at implementation and then monitor these processes on a regular basis, using quality control methods.

Manufacturing biologic products, including Whole Blood and blood components, comes with specific challenges due to biologic variability and the potential risk to recipients if products are not manufactured appropriately. Recognizing these issues, FDA has developed statistical plans that are capable of identifying when the manufacturing process varies or has a high frequency of nonconformance.

The goal of the workshop is to educate participants on statistical process control theory and options for the implementation of scientifically sound sampling plans in blood establishments. The public workshop will include presentations and discussions on the following topics: (1) The evolution of statistical process control for Whole Blood and blood components; (2) statistical methods used for biologic product quality control; (3) FDA considerations for

sampling plans for blood establishments; and (4) industry perspectives and case studies on implementing statistical process controls.

*Transcripts:* Please be advised that a transcript of the public workshop will be posted as soon as possible on the Internet at: <http://www.fda.gov/Biologics/BloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm>. Transcripts of the public workshop may also be requested in writing from the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857.

Dated: July 27, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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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, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes 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 and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Officer at (301) 443-1984.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the Agency; (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.

#### Telehealth Resource Center Performance Measurement Tool (OMB No. 0915-xxxx)-[New]

To ensure the best use of public funds and to meet the Government Performance Review Act (GPRA) requirements, HRSA's Office for the Advancement of Telehealth (OAT), in collaboration with the Telehealth Resource Centers (TRCs), created a set of performance measures that grantees can use to evaluate the technical assistance services provided by the TRCs. Grantee goals are to customize the provision of telehealth technical assistance across the country. The TRCs provide technical assistance to health care organizations, health care networks and health care providers in the implementation of cost-effective telehealth programs to serve rural and medically underserved areas and populations. The TRC Performance Indicator Data Collection Tool contains the data elements that would need to be collected by the TRCs in order to report on the performance metrics. This tool can be easily translated into the web-based data collection system, Performance Improvement and Measurement System (PIMS). Reporting via PIMS allows the TRCs and OAT to track project performance. The tool assists in the production of annual reports, available to Congress, that demonstrate the value added from the TRC Grant Program.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Telehealth Resource Center Performance Data Collection Tool .....	14	72	1,008	0.07	70.56
Total .....	14	.....	1,008	.....	70.56