Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Amendment to Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components Intended for Transfusion; Draft Guidance for Industry.'' The draft guidance, when finalized, is intended to amend the 2010 Chagas Guidance (75 FR 75810, December 6, 2010) by expanding the scope of the guidance to include the collection of blood and blood components for use in manufacturing a product, including donations intended as a component of, or used to manufacture, a medical device; removing the recommendation to ask donors about a history of Chagas disease; and providing a recommendation for a reentry algorithm for donors deferred on the basis of screening test results for antibodies to *T. cruzi* or on the basis of answering ''yes'' to the Chagas screening question.

In the **Federal Register** of May 22, 2015 (80 FR 29842), FDA published the final rule entitled ''Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use.'' The final rule became effective May 23, 2016. The draft guidance is intended to notify blood establishments that collect blood and blood components that *T. cruzi* is defined as a relevant transfusion-transmitted infection in 21 CFR 630.3(h)(1), subject to the testing requirements in 21 CFR 610.40, the donor deferral practices in 21 CFR 610.41, and the donor notification requirements in 21 CFR 630.40 under the final rule. In addition, the draft guidance is intended to notify blood establishments that collect blood and blood components that FDA has licensed a supplemental test for antibodies to *T. cruzi* and further testing of donations found repeatedly reactive to a screening test for *T. cruzi* is therefore required under 21 CFR 610.40(e). The draft guidance does not apply to the collection of Source Plasma. All other recommendations in the 2010 Chagas Guidance would remain unchanged.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Amendment to Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components Intended for Transfusion; Draft Guidance for Industry.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338; and the collections of information in 21 CFR 610.40 and 630.40 have been approved under OMB control numbers 0910–0116 and 0910–0795.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: November 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–27107 Filed 11–9–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health IT Standards Committee Advisory Meeting; Notice of Meeting

AGENCY: Office of the National Coordinator for Health Information Technology, HHS.

ACTION: Notice of meeting

This notice announces updated dates for meetings of a public advisory committee of the Office of the National Coordinator for Health Information Technology (ONC). These meetings are open to the public.

Name of Committee: Health IT Standards Committee.

General Function of the Committee: To provide recommendations to the National Coordinator on standards, implementation specifications, and certification criteria for the electronic exchange and use of health information for purposes of adoption, consistent with the implementation of the Federal Health IT Strategic Plan, and in accordance with policies developed by the Health IT Policy Committee.

2016 Meeting Dates and Times

- December 6, 2016 from 9:30 a.m. to 1:30 p.m./Eastern Time (replacing the formerly announced November 2 and December 7 meetings)
  - This will be a virtual Joint Health IT Policy and Health IT Standards Committee meeting

For meeting locations, web conference information, and the most up-to-date information, please visit the calendar on the ONC Web site, *http://www.healthit.gov/FACAS/calendar.*

Contact Person: Michelle Consolazio, email: *michelle.consolazio@hhs.gov.* Please email Michelle Consolazio for the most current information about meetings. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

Agenda: The committee will hear reports from its workgroups/task forces and updates from ONC and other federal agencies. ONC intends to make background material available to the public no later than 24 hours prior to the meeting start time. If ONC is unable to post the background material on its Web site prior to the meeting, it will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on ONC's Web site after the meeting, at *http://www.healthit.gov/facas/health-it-standards-committee.*

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. Written submissions may be made to the contact person prior to the meeting date. Oral comments from the public will be scheduled prior to the lunch break and at the conclusion of each meeting. Time allotted for each presentation will be limited to three minutes. If the number of speakers requesting to comment is greater than can be reasonably accommodated during the scheduled open public session, ONC will take written comments after the meeting.

Persons attending ONC's advisory committee meetings are advised that the agency is not responsible for providing wireless access or access to electrical outlets.

ONC welcomes the attendance of the public at its advisory committee meetings. Seating is limited at the location, and ONC will make every effort to accommodate persons with

physical disabilities or special needs. If you require special accommodations due to a disability, please contact Michelle Consolazio at least seven (7) days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App. 2).

Dated: October 31, 2016.

Michelle Consolazio,

FACA Program Director, Office of Policy, Office of the National Coordinator for Health Information Technology.

[FR Doc. 2016–27172 Filed 11–9–16; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health IT Policy Committee Advisory Meeting; Notice of Meeting

AGENCY: Office of the National Coordinator for Health Information Technology, HHS.

ACTION: Notice of meeting.

This notice announces updated dates for meetings of a public advisory committee of the Office of the National Coordinator for Health Information Technology (ONC). These meetings are open to the public.

Name of Committee: Health IT Policy Committee.

General Function of the Committee: To provide recommendations to the National Coordinator on a policy framework for the development and adoption of a nationwide health information technology infrastructure that permits the electronic exchange and use of health information as is consistent with the Federal Health IT Strategic Plan and that includes recommendations on the areas in which standards, implementation specifications, and certification criteria are needed.

2016 Meeting Dates and Times

- November 3, 2016 from 9:30 a.m. to 3:00 p.m./Eastern Time (Cancelled)
- December 6, 2016 from 9:30 a.m. to 1:30 p.m./Eastern Time
  - This will be a virtual Joint Health IT Policy and Health IT Standards Committee meeting

For meeting locations, web conference information, and the most up-to-date information, please visit the calendar on the ONC Web site, *http://www.healthit.gov/FACAS/calendar.*

Contact Person: Michelle Consolazio, email: *michelle.consolazio@hhs.gov.* Please email Michelle Consolazio for the most current information about meetings. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

Agenda: The committee will hear reports from its task forces and updates from ONC and other federal agencies. ONC intends to make background material available to the public no later than 24 hours prior to the meeting start time. If ONC is unable to post the background material on its Web site prior to the meeting, it will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on ONC's Web site after the meeting, at *http://www.healthit.gov/FACAS/health-it-policy-committee.*

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. Written submissions may be made to the contact person prior to the meeting date. Oral comments from the public will be scheduled prior to the lunch break and at the conclusion of each meeting. Time allotted for each presentation will be limited to three minutes. If the number of speakers requesting to comment is greater than can be reasonably accommodated during the scheduled open public session, ONC will take written comments after the meeting.

Persons attending ONC's advisory committee meetings are advised that the agency is not responsible for providing wireless access or access to electrical outlets.

ONC welcomes the attendance of the public at its advisory committee meetings. Seating is limited at the location, and ONC will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Michelle Consolazio at least seven (7) days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App. 2).

Dated: October 31, 2016.

Michelle Consolazio,

FACA Program Director, Office of Policy, Office of the National Coordinator for Health Information Technology.

[FR Doc. 2016–27174 Filed 11–9–16; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; 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: National Institute of Environmental Health Sciences Special, Emphasis Panel; E-Learning Review Meeting.

Date: November 29, 2016.

Time: 11:30 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NIEHS/National Institutes of Health, Keystone Building, Room 2128, 530 Davis Drive, Research Triangle Park, NC 27709 (Telephone Conference Call).

Contact Person: Janice B. Allen, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Science, P.O. Box 12233, MD EC–30/Room 3170 B, Research Triangle Park, NC 27709, 919/541–7556.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; R13 Conference Grant Applications Review Meeting Group 1.

Date: November 30, 2016.

Time: 11:30 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NIEHS/National Institutes of Health, Keystone Building, Room 2128, 530 Davis Drive, Research Triangle Park, NC 27709 (Telephone Conference Call).

Contact Person: Janice B. Allen, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Science, P.O. Box 12233, MD EC–30/Room 3170 B Research Triangle Park, NC 27709, 919/541–7556.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to