interested in assessing potential trial participants' interest, tolerance, concerns, and willingness to participate in clinical investigations that involve nontraditional settings or utilize new technologies. FDA is also interested in identifying the factors that affect trial participant awareness, acceptance, enrollment, and retention for these investigations.

a. Are there specific patient groups or therapeutic areas that could particularly benefit from these types of technologies or methods?

b. What new opportunities for the conduct of clinical investigations are created through the use of continuous or intermittent remote monitoring and data collection?

c. What are some of the anticipated risks to trial participants that may occur as a result of the use of these technologies or off-site methods in clinical investigations?

d. What are some of the anticipated benefits to trial participants that may occur as a result of the use of these technologies or off-site methods in clinical investigations?

e. Are there perceived challenges to participation in clinical investigations utilizing these types of technologies or methods because of concerns regarding inadvertent disclosure of trial participants' information or breach of privacy? Are there concerns relating to the integrity of data collection or encryption or the secure transmission of information?

f. Are there unique considerations for ensuring integrity of the source data, for example, authenticity and reliability?

g. How should validation of participant-operated mobile devices be addressed?

h. What are the challenges presented when data are collected using the Bring Your Own Device (BYOD) model? BYOD in clinical investigations refers to the practice of trial participants using their own devices, such as smartphones or tablets, for data collection. For example, participants in a clinical investigation may use their own computer devices to access and respond to study-related questionnaires. What are the perceived barriers to pooling data collected from different devices provided by individual trial participants, as well as pooling data from the BYOD model with data collected at the investigational site or on paper forms? How should situations such as mid-study user device switches be handled?

i. What are the challenges or special considerations with recruiting and/or retaining potential trial participants with low levels of computer literacy or individuals who may have limited or no access to mobile technologies, computer devices, or the Internet? How can these challenges or special considerations best be addressed?

Dated: October 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27581 Filed 10–28–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–2138]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on Adverse Event Reporting for Outsourcing Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry on Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug and Cosmetic Act'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On August 4, 2015, the Agency submitted a proposed collection of information entitled ''Guidance for Industry on Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0800. The approval expires on September 30, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: *October 23, 2015.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27557 Filed 10–28–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 80 FR 44358 dated July 27, 2015).

This notice reflects organizational changes in the Health Resources and Services Administration (HRSA), Office of Planning, Analysis, and Evaluation (RA5). Specifically, this notice: (1) Establishes the Office of Strategic Initiatives (RA59) within the Office of Planning, Analysis, and Evaluation.

Chapter RA5—Office of Planning, Analysis, and Evaluation

Section RA5—00, Mission

The Office of Planning, Analysis, and Evaluation (RA5) provide HRSA-wide leadership on cross-agency initiatives and Departmental priorities.

Section RA5–10, Organization

Delete the organization for the Office of Planning, Analysis, and Evaluation in its entirety and replace with the following:

The Office of Planning, Analysis, and Evaluation (RA5) is headed by the Director, who reports directly to the Administrator, Health Resources and Services Administration. The Office of Planning, Analysis, and Evaluation includes the following components:

(1) Office of the Director (RA5);

(2) Office of Policy Analysis (RA53);

(3) Office of Research and Evaluation (RA56);

(4) Office of External Engagement (RA57);

(5) Office of Performance and Quality Measurement (RA58); and

(6) Office of Strategic Initiatives (RA59).

Section RA5–20, Functions

This notice reflects organizational changes in the Health Resources and Services Administration (HRSA), Office