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

of Planning, Analysis, and Evaluation (RA5). Specifically, this notice: (1) Establishes the Office of Strategic Initiatives (RA59).

Establish the functional statement for the Office of Strategic Initiatives (RA59) within the Office of Planning, Analysis, and Evaluation (RA5).

Office of Strategic Initiatives (RA59)

(1) Provides HRSA-wide leadership on cross-agency initiatives and departmental priorities; (2) maintains liaison between the Administrator, other OPDIVs, Office of the Secretary staff components, and other Departments on priority initiatives; (3) provides technical assistance to Agency programs in order to help them respond to emerging issues affecting the health care safety net; (4) coordinates outreach to grantees and stakeholders on high profile public health initiatives; (5) establishes an infrastructure and strategic direction of priority initiatives and institutionalizes these efforts into HRSA programs; and (6) coordinates the Agency's long-term strategic planning process.

Delegations of Authority

All delegations of authority and re-delegations of authority made to HRSA officials that were in effect immediately prior to this reorganization, and that are consistent with this reorganization, shall continue in effect pending further re-delegation.

This reorganization is effective upon date of signature.

Dated: October 18, 2015.

James Macrae,

Acting Administrator.

[FR Doc. 2015–27592 Filed 10–28–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Dr. Maria C.P. Geraedts, University of Maryland, Baltimore: Based on the report of an investigation conducted by the University of Maryland, Baltimore (UMB) and analysis conducted by ORI in its oversight review, ORI and UMB found that Dr. Maria C.P. Geraedts, former postdoctoral fellow, Department of Anatomy and Neurobiology, UMB, engaged in research misconduct in research supported by National Institute on Deafness and Other Communication Disorders (NIDCD), National Institutes of Health (NIH), grant R01 DC010110.

ORI found falsified and/or fabricated data included in the following two (2) publications:

- *Am J Physiol Endocrinol Metab* 303:E464–E474, 2012 (hereafter referred to as ''*AJP* 2012'')
- *Journal of Neuroscience* 33(17):7559–7564, 2013 (hereafter referred to as ''*JN* 2013'')

As a result of the UMB investigation, *JN* 2013 and *AJP* 2012 have been retracted.

ORI found that Respondent falsified and/or fabricated bar graphs in *AJP* 2012, by changing ELISA-based measurements to produce the desired result for secretion of glucagon-like peptide-1 (GLP–1) from intestinal explants from various mouse strains in:

- Figure 2 for GLP–1 release from duodenum (2A & D), jejunum (2B & E), and ileum (2C & F).
- Figure 3 for GLP–1 release from colon (3A & C) and rectum (3D).
- Figure 4 for GLP–1 release from ileum (4A) and colon (4C) in the presence or absence of an ATP-sensitive K+ channel inhibitor.

ORI found that Respondent falsified and/or fabricated bar graphs in Figure 1, *JN* 2013 by changing ELISA-based measurements to produce the desired result for the secretion of peptides found in taste buds (GLP–1, glucagon, or neuropeptide Y) from mouse lingual epithelium exposed to various concentrations of stimuli (glucose, sucralose, MSG, polycose). These bar graphs also were included as Figure 7 in grant application R01 DC010110–06.

Both the Respondent and the U.S. Department of Health and Human Services (HHS) want to conclude this matter without further expenditure of time or other resources and have entered into a Voluntary Settlement Agreement (Agreement) to resolve this matter. Respondent stated that she is not currently involved in U.S. Public Health Service (PHS)-supported research and has no intention of applying for or engaging in PHS-supported research or otherwise working with PHS. Dr. Geraedts has entered into a Voluntary Settlement Agreement with ORI and UMB, in which she voluntarily agreed to the administrative actions set forth below. The administrative actions are required for three (3) years beginning on the date of Dr. Geraedts employment in a position in which she receives or applies for PHS support on or after the effective date of the Agreement (September 22, 2015). If the Respondent has not obtained employment in a research position in which she receives or applies for PHS support within one (1) year of the effective date of the Agreement, the administrative actions set forth below will no longer apply. Dr. Geraedts has voluntarily agreed:

(1) To have her research supervised as described below and notify her employer(s)/institution(s) of the terms of this supervision; Respondent agreed that prior to the submission of an application for PHS support for a research project on which her participation is proposed and prior to her participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of her duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of her research contribution; Respondent agreed that she will not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed upon supervision plan;

(2) that any institution employing her shall submit in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived, and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract; and

(3) to exclude herself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for period of three (3) years beginning on September 22, 2015.

FOR FURTHER INFORMATION CONTACT: Acting Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8200.

Donald Wright,

Acting Director, Office of Research Integrity.

[FR Doc. 2015–27587 Filed 10–28–15; 8:45 am]

BILLING CODE 4150–31–P