

and falsifying patient data in research supported by National Institute on Aging (NIA), National Institutes of Health (NIH), grant R01 AG18461.

Specifically, Ms. Okoro intentionally and knowingly fabricated and falsified data for six visit dates on one patient data form and falsified and fabricated patient condition information on two additional study subjects by failing to note that each patient had experienced a fall as documented in their medical charts.

ORI has implemented the following administrative actions for a period of three (3) years, beginning July 17, 2006:

(1) Ms. Okoro is prohibited 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; and

(2) Any institution that submits an application for PHS support for a research project on which Ms. Okoro's participation is proposed or which uses her services in any capacity on PHS supported research must concurrently submit a plan for supervision of her duties. The supervisory plan must be designed to ensure the scientific integrity of Ms. Okoro's research contribution and must be submitted to ORI by the institution.

FOR FURTHER INFORMATION CONTACT:

Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453-8800.

Chris B. Pascal, J.D.,

Director, Office of Research Integrity.

[FR Doc. E6-12857 Filed 8-7-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Science Advisory Board to the National Center for Toxicological Research; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Science Advisory Board (SAB) to the National Center for Toxicological Research (NCTR).

General Function of the Committee: The Board advises the Director, NCTR,

in establishing, implementing, and evaluating the research programs that assist the Commissioner of Food and Drugs in fulfilling his regulatory responsibilities. The Board provides an extra-agency review in ensuring that the research programs at NCTR are scientifically sound and pertinent.

Date and Time: The meeting will be held on August 29, 2006 from 8:30 a.m. to 4:30 p.m. and on August 30, 2006, from 8 a.m. to 12 noon.

Location: August 29, 2006: NCTR SAB Conference Room B-12, 3900 NCTR Dr., Jefferson, AR 72079. August 30, 2006: University of Arkansas for Medical Sciences, Stephens Spine Center, Hamlin Board Room, 501 Jack Stephens Dr., Little Rock, AR 72205.

Contact Person: Leonard Schechtman, Executive Secretary, National Center for Toxicological Research, Food and Drug Administration, 5600 Fishers Lane, rm. 16-85, Rockville, MD 20857, 301-827-6696, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512559. Please call the Information Line for up-to-date information on this meeting.

Agenda: On August 29, 2006, the SAB will hear presentations from the NCTR Divisions that will update them on ongoing research activities. The SAB will be presented with a response to the evaluation of the Division of Neurotoxicology. The evaluation was the product of a site visit team that conducted an on-site review of the Division in January 2004. The response will address the issues raised and recommendations made by the site visit team. On August 30, 2006, the NCTR Director will provide a Center-wide update on scientific endeavors and will discuss the NCTR realignment and strategic focus.

Procedure: On August 29, 2006, from 8:30 a.m. to 4:30 p.m., and August 30, 2006, from 8 a.m. to 10:30 a.m., the meeting is open to the public. 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 on or before August 14, 2006. Oral presentations from the public will be scheduled on August 29, 2006, between approximately 12:30 p.m. to 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should likewise notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time

requested to make their presentation on or before August 14, 2006.

Closed Committee Deliberations: On August 29, 2006, from approximately 11 a.m. to 12:30 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion of the meeting will be closed to permit discussion of information concerning individuals associated with the research programs at NCTR.

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

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact the office of the Executive Secretary at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 2, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1992S-0251] (formerly 92S-0251)

Food and Drug Administration Electronic Submissions Gateway

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the FDA Electronic Submissions Gateway (ESG) for the receipt and processing of electronic submissions provided so that the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), and the Center for Devices and Radiological Health (CDRH) can receive regulatory submissions electronically. The FDA ESG enables applicants to send applications and other submissions for review using the Internet, provides a single point of entry for these submissions, and fulfills goals identified in the Prescription Drug User Fee Act (PDUFA III).