

and falsifying data in Figure 3 of a paper published in *Endocrinology*.¹ Specifically, PHS found that:

- Respondent, by not conducting any of the claimed bisulfite sequencing, fabricated the methylation status of CpG sites in eight candidate genes identified in both Figures 3 and 4 as No. 11, No. 12, No. 13, No. 14, 15, No. 22, No. 26, No. 31, and No. 19, to support the hypothesis that the environmental compound, vinclozolin, induces a permanent alteration in the epigenetic reprogramming of the germline that promotes transgenerational disease states.

- Respondent, by conducting only a small fraction of the claimed bisulfite sequencing, and falsifying the results obtained, falsified the methylation status of CpG sites in eight additional candidate genes, identified in Figures 3 and 4 as No. 2, 3, 24, No. 5, 6, 9, No. 8, No. 16, No. 17, 18, No. 27, 28, No. 29, and No. 33.

Dr. Chang has entered into a Voluntary Settlement Agreement in which he has voluntarily agreed, for a period of three (3) years, beginning on July 21, 2010:

(1) To exclude himself 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;

(2) that any institution that submits an application for PHS support for a research project on which the Respondent's participation is proposed or that uses him in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which the Respondent is involved, must concurrently submit a plan for supervision of the Respondent's duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of the Respondent's research contribution while applying for or conducting PHS-supported research. Respondent agrees to ensure that a copy of the supervisory plan is submitted to ORI by the institution for ORI approval. Respondent agrees not to participate in any PHS-supported research until such a supervisory plan is submitted to ORI.

FOR FURTHER INFORMATION CONTACT:

Director, Division of Investigative Oversight, Office of Research Integrity,

1101 Wootton Parkway, Suite 750,
Rockville, MD 20852, (240) 453-8800.

John Dahlberg,

*Director, Division of Investigative Oversight,
Office of Research Integrity.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of the Assistant Secretary for Health; Statement of Organization, Functions, and Delegations of Authority

Part A, Office of the Secretary, Statement of Organizations, Functions and Delegations of Authority for the Department of Health and Human Services (HHS) is being amended at Chapter AA, "Immediate Office of the Secretary," which was last amended at 75 FR 20364-65, dated April 19, 2010, and at Chapter AC, "Office of Public Health and Science (OPHS)," which was last amended at 72 FR 58095-96, dated October 12, 2007. This amendment will accomplish two tasks: (1) In Chapter AC, revise the title of the office headed by the Assistant Secretary for Health (ASH) from the "Office of Public Health and Science" to the "Office of the Assistant Secretary for Health," and; (2) add information about a new office reporting to the Assistant Secretary for Health (ASH), the "Office of Adolescent Health," established in section 1708 of the Public Health Service (PHS) Act (42 U.S.C. 300u-7), and most recently addressed in the December 8, 2009, Conference Report (House Report 111-366) accompanying the Consolidated Appropriations Act, 2010 (Pub. L. 111-117). The changes are as follows:

A. Under Part A, Chapter AA, Section AA.10 Organization, replace the "Office of Public Health and Science (AC)" with the "Office of the Assistant Secretary for Health (AC)."

B. Under Part A generally and Part A, Chapter AC, replace all references to the "Office of Public Health and Science" with the "Office of the Assistant Secretary for Health" and all references to "OPHS" with "OASH."

C. Under Part A, Chapter AC, Section AC.10 Organization, insert "M. Office of Adolescent Health (ACR)" immediately after "L. Office of Commissioned Corps Force Management (ACQ)."

D. Under Part A, Chapter AC, Section AC.20 Functions, insert the following text immediately after item, "L. Office of Commissioned Corps Force Management (ACQ)":

M. Office of Adolescent Health (ACR)

Section ACR.00 Mission. The Director of the Office of Adolescent Health (OAH) is the principal advisor to the Assistant Secretary for Health (ASH) on health-related policy and program issues related to adolescents. These issues cut across Health and Human Services (HHS) components which provide research, services, prevention, promotion, treatment, training, education, and information dissemination related to adolescent health. OAH is responsible for implementing activities authorized by section 1708 of the Public Health Service (PHS) Act.

Section ACR.10 Organization. The Office of Adolescent Health is headed by a Director who reports to the Assistant Secretary for Health and includes the following components:

A. Immediate Office of the Director (ACR)

B. Division of Program Development and Operations (ACR1)

C. Division of Policy, Planning, and Communications (ACR2)

Section ACR.20 Functions

1. Immediate Office of the Director (ACR). The Immediate Office of the Director (IOD) plans and directs financial management and policy development, including budget formulation and execution. The IOD also oversees legislative activities related to adolescent health, acts as a liaison on personnel management to the Office of the Assistant Secretary for Health (OASH) and the Program Support Center, and coordinates correspondence control and executive secretariat functions for OAH. The IOD also manages the day-to-day operations of OAH, plans, coordinates, monitors, and evaluates OAH grants and contracts, and ensures the appropriate exercise of delegated authorities and responsibilities.

2. Division of Program Development and Operations (ACR1). The Division of Program Development and Operations (DPDO) advises the OAH Director on the development of new programs and policies, oversees the implementation and administration of competitive grants and cooperative agreements, monitors grantee activities, evaluates the focus and impact of ongoing programs, prepares analytical reports on program trends, provides training and technical assistance for grant programs, and assesses performance of grantee operations. The Division manages the development of funding announcements and contract scopes of work and the review and award of program grants,

¹ Chang, H.S., Anway, M.D., Rekow, S.S., & Skinner, M.K. "Transgenerational epigenetic imprinting of the male germline by endocrine disruption exposure during gonadal sex determination." *Endocrinology* 147(12):5524-5541; hereafter referred to as the "Endocrinology paper."

cooperative agreements, and contracts. The Division also provides for training of health professionals who work with adolescents, particularly nurse practitioners, physician assistants, and social workers.

3. Division of Policy, Planning, and Communications (ACR2). The Division of Policy, Planning, and Communications (DPPC) is the primary information source on adolescent health programs of OAH. The Division: advises the OAH Director on policy issues; manages information, education and awareness activities and media and press relations; develops and coordinates strategic plans and special initiatives; oversees public health information and performance measurement; and coordinates and promotes OAH programs and policies. DPPC oversees and directs the OAH's communication programs, consistent with the policies of the HHS Assistant Secretary for Public Affairs. This Division also coordinates, develops, researches, and prepares briefing materials on adolescent health for the OAH Director and other HHS offices.

E. Under Part A, Chapter AC, Section AC.10 Organization, replace all references to the "Office of the President's Council on Physical Fitness and Sports (ACE)" with the "Office of the President's Council on Fitness, Sports and Nutrition (ACE)" and all references to the "President's Council on Physical Fitness and Sports" with the "President's Council on Fitness, Sports and Nutrition."

F. Under Part A, Chapter AC, Section AC.20 Functions, Paragraph A, "The Immediate Office (ACA)," insert the following after "(18)":

(19) leads and coordinates public health activities that addresses health disparities related to sexual orientation.

Dated: July 29, 2010.

Kathleen Sebelius,
Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "AHRQ Grants Reporting System (GRS)." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3520, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by November 1, 2010.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by e-mail at doris.lefkowitz@AHRQ.hhs.gov.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by e-mail at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

AHRQ Grants Reporting System (GRS)

AHRQ seeks to renew the Agency's Grants Reporting System (GRS), a systematic method for its grantees to report project progress and important preliminary findings for grants funded by the Agency. This system was first approved by OMB on November 10th, 2004 (OMB Control Number 0935-0122). The system addressed the shortfalls in the previous reporting process and established a consistent and comprehensive grants reporting solution for AHRQ. The GRS provides a centralized repository of grants research progress and additional information that can be used to support initiatives within the Agency. This includes future research planning and support to administration activities such as performance monitoring, budgeting, knowledge transfer as well as strategic planning.

The overall intent of the GRS project is to establish and document a systematic process that provides grantees with the ability to submit critical information in a timely manner throughout the lifecycle of a grant. In addition, the GRS project includes an infrastructure that is scalable and flexible to support information exchange throughout the Agency.

The GRS is based on a review of the previous processes that supported the solicitation and submission of data

associated with patient safety grants. Following this review, a recommended process was prepared and presented to AHRQ stakeholders. The project team developed an initial system that addresses the immediate needs of the stakeholder community.

The project team, in conjunction with the stakeholder community will establish follow-on activities which will expand the capabilities of the initial system to meet the longer term goals of the project as directed by the executive management team of the agency. The specific activities that were accomplished in the short term and those established for the longer term are outlined below.

Short-Term Objectives

The following initial objectives for the GRS project have been:

- Establish and document a systematic process which supports the voluntary reporting of project progress and important preliminary findings associated with patient safety research grants.
- Collect, document, and prioritize the long-term objectives of the GRS.
- Establish an infrastructure that satisfies the short-term objectives of the project and can be leveraged to meet the long-term objectives and anticipated expansion.
- Establish an automated user-friendly resource that will be used by grantees, regardless of mechanism, for reporting to AHRQ.
- Establish an automated user-friendly resource that will be utilized by Agency staff for preparing, distributing, and reviewing reporting requests to patient safety grantees.
- Ensure that the necessary security requirements are established and implemented in order to maintain the intellectual property or publication rights of grantees.
- Establish a solution that is consistent with the AHRQ enterprise architecture model and aligned with AHRQ systems development standards.

Long-Term Objectives

The AHRQ project team will continue to enhance the GRS to establish a single, common reporting system for research related activities by:

- Enhancing the initial system as necessary to accommodate features not addressed by the short-term solution.
- Modifying the short-term solution to address new requirements and refine existing functionality for use across the agency for other programs and mechanisms.
- Expanding the deployment of the system to accommodate additional