

Appendix C

42 U.S.C. § 289b

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary; Office of Public Health and Science

Statement of Organization, Functions, and Delegations of Authority

Part A, (Office of the Secretary) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Chapter AC, Office of Public Health and Science (OPHS), paragraph ACA, Immediate Office, as last amended at 62 FR 5009–10, 2/3/97; and paragraph ACF, Office of Research Integrity (ORI), as last amended at 60 FR 56606–06, dated November 9, 1995, are being amended to make policy changes approved by the Secretary. Specifically, the Notice is to reflect that the Assistant Secretary for Health (ASH) will make proposed findings of research misconduct and administrative actions in response to allegations of research misconduct involving research conducted or supported by components of the Public Health Service (PHS); that direct investigations, previously conducted by ORI, will be conducted by components of the PHS for intramural research and by the Office of Inspector General for extramural research; and that role and structure of ORI will be changed to focus more on preventing misconduct and promoting research integrity through expanded education programs. The changes are as follows:

I. Amend Chapter AC.20 Functions, paragraph A. “Office of Public Health and Science,” paragraph titled, “The Immediate Office (ACA)” by adding the following new clause:

(1) Proposes findings of research misconduct and administrative actions in response to allegations of research misconduct involving research conducted or supported by the Public Health Service (PHS) OPDIVs, including reversal of an institution’s no misconduct finding or opening of a new investigation.

II. Under Section AC.20 Function, delete, paragraph E. “Office of Research Integrity (ACF)” in its entirety, and replace with the following:

E. Office of Research Integrity (ACF)—The Director reports to the Secretary and will: (1) Oversee and direct Public Health Service (PHS) research integrity activities on behalf of the Secretary with the exception of the regulatory research integrity activities of the Food and Drug Administration; (2) recommend to the Assistant Secretary for Health for decision, findings of research misconduct and administrative actions in connection with research conducted or supported by the PHS; (3) coordinate the development of research integrity policies designed to ensure that subjects of investigations and whistleblowers are treated fairly, including clear specification of what constitutes misconduct, a fair hearing process, appropriate time limits on pursuing allegations, and specific whistleblower protections; (4) manage the financial resources and provide overall administrative guidance in carrying out the activities; and (5) oversee and direct the research misconduct and integrity activities of the office, including the oversight of research misconduct inquiries and investigations, education and training in the responsible conduct of research, activities designed to promote research integrity and prevent misconduct, and research and evaluation programs.

1. Division of Education and Integrity (ACF2)—The Director and staff: (1) develop and implement, in consultation with the PHS OPDIVs, activities and programs for PHS intramural and extramural research to teach the responsible conduct of research, promote research integrity, prevent research misconduct, and to enable the extramural institutions and PHS OPDIVs to respond effectively to allegations of research misconduct; (2) coordinate the dissemination of research integrity policies, procedures, and regulations; (3) conduct policy analyses, evaluations, and research to improve DHHS research integrity policies and procedures and build the knowledge base in research misconduct, research integrity, and prevention; (4) develop (in consultation with the PHS OPDIVs) policies, procedures, and regulations for review by the Director, Office of Research Integrity, and recommendations to the Secretary; (5) administer programs for: approval of institutional assurances; response to Freedom of Information Act and Privacy Act requests; review and approval of intramural and extramural policies and procedures; and response to allegations of whistleblower retaliation.

2. Division of Investigative Oversight (ACF3)—The Director and staff: (1) review and monitor investigations conducted by applicant and awardee institutions and intramural research programs; (2) evaluate investigations and investigatory findings of awardee and applicant institutions, intramural research programs, and the Office of Inspector General and develop and recommend to the ORI Director, findings of research misconduct and

proposal administrative actions against those who committed misconduct; (3) assist the Office of the General Counsel (OGC) in preparing and presenting cases in hearings before the Research Integrity Adjudications Panel of the DHHS Department Appeals Board; (4) provide information on DHHS policies and procedures, as requested, to individuals who have made an allegation or have been accused of research misconduct; and (5) establish and implement a program of advice and technical assistance to entities that conduct inquiries and investigations, or otherwise respond to allegations of research misconduct.

III. Under Chapter AC, Section ACF- 30, Delegations of Authority—All delegations and redelegations of authority to the Assistant Secretary for

Health and officials of the Office of Research Integrity that were in effect prior to the effective date of this reorganization shall continue in effect pending further redelegation.

Dated: April 14, 2000. **Betsy D'Jamos,**

Acting Assistant Secretary for Management and Budget.

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