

## Appendix B

### 42 CFR part 50 and 93

42 U.S.C. § 289b

Establishment of Office

#### § 289b. Office of Research Integrity

- (a) In general
  - (1) Establishment of Office

Not later than 90 days after June 10, 1993, the Secretary shall establish an office to be known as the Office of Research Integrity (referred to in this section as the "Office"), which shall be established as an independent entity in the Department of Health and Human Services.

- (2) Appointment of Director

The Office shall be headed by a Director, who shall be appointed by the Secretary, be experienced and specially trained in the conduct of research, and have experience in the conduct of investigations of research misconduct. The Secretary shall carry out this section acting through the Director of the Office. The Director shall report to the Secretary.

- (3) Definitions
  - (A) The Secretary shall by regulation establish a definition for the term "research misconduct" for purposes of this section.
  - (B) For purposes of this section, the term "financial assistance" means a grant, contract, or cooperative agreement.

- (b) Existence of administrative processes as condition of funding for research

The Secretary shall by regulation require that each entity that applies for financial assistance under this chapter for any project or program that involves the conduct of biomedical or behavioral research submit in or with its application for such assistance -

- (1) assurances satisfactory to the Secretary that such entity has established and has in effect (in accordance with regulations which the Secretary shall prescribe) an administrative process to review reports of research misconduct in connection with biomedical and behavioral research conducted at or sponsored by such entity;
- (2) an agreement that the entity will report to the Director any investigation of alleged research misconduct in connection with projects for which funds have been made available under this chapter that appears substantial; and
- (3) an agreement that the entity will comply with regulations issued under this section.

- (c) Process for response of Director

The Secretary shall by regulation establish a process to be followed by the Director for the prompt and appropriate -

- (1) response to information provided to the Director respecting research misconduct in connection with projects for which funds have been made available under this chapter;

- o (2) receipt of reports by the Director of such information from recipients of funds under this chapter;
  - o (3) conduct of investigations, when appropriate; and
  - o (4) taking of other actions, including appropriate remedies, with respect to such misconduct.
- (d) Monitoring by Director

The Secretary shall by regulation establish procedures for the Director to monitor administrative processes and investigations that have been established or carried out under this section.

- (e) Protection of whistleblowers
  - o (1) In general

In the case of any entity required to establish administrative processes under subsection (b) of this section, the Secretary shall by regulation establish standards for preventing, and for responding to the occurrence of retaliation by such entity, its officials or agents, against an employee in the terms and conditions of employment in response to the employee having in good faith -

- (A) made an allegation that the entity, its officials or agents, has engaged in or failed to adequately respond to an allegation of research misconduct; or
  - (B) cooperated with an investigation of such an allegation.
- o (2) Monitoring by Secretary

The Secretary shall by regulation establish procedures for the Director to monitor the implementation of the standards established by an entity under paragraph (1) for the purpose of determining whether the procedures have been established, and are being utilized, in accordance with the standards established under such paragraph.

- o (3) Noncompliance

The Secretary shall by regulation establish remedies for noncompliance by an entity, its officials or agents, which has engaged in retaliation in violation of the standards established under paragraph (1). Such remedies may include termination of funding provided by the Secretary for such project or recovery of funding being provided by the Secretary for such project, or other actions as appropriate.