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42 CFR Ch. I (10–1–03 Edition)

(1) There is an effect at that Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the PHS,

(2) Prior to the Institution's expenditure of any funds under the award, the Institution will report to the PHS Awarding Component the existence of a conflicting interest (but not the nature of the interest or other details) found by the institution and assure that the interest has been managed, reduced or eliminated in accordance with this subpart; and, for any interest that the Institution identifies as conflicting subsequent to the Institution's initial report under the award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on an interim basis, within sixty days of that identification;

(3) The Institution agrees to make information available, upon request, to the HHS regarding all conflicting interests identified by the Institution and how those interests have been managed, reduced, or eliminated to protect the research from bias; and

(4) The Institution will otherwise comply with this subpart.

§ 50.605 Management of conflicting interests.

(a) The designated official(s) must: Review all financial disclosures; and determine whether a conflict of interest exists and, if so, determine what actions should be taken by the institution to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:

(1) Public disclosure of significant financial interests;

(2) Monitoring of research by independent reviewers;

(3) Modification of the research plan;

(4) Disqualification from participation in all or a portion of the research funded by the PHS;

(5) Divestiture of significant financial interests; or

(6) Severance of relationships that create actual or potential conflicts.

(b) In addition to the types of conflicting financial interests described in this paragraph that must be managed, reduced, or eliminated, an Institution may require the management of other conflicting financial interests, as the Institution deems appropriate.

§ 50.606 Remedies.

(a) If the failure of an Investigator to comply with the conflict of interest policy of the Institution has biased the design, conduct, or reporting of the PHS-funded research, the Institution must promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the funded project.

(b) The HHS may at any time inquire into the Institutional procedures and actions regarding conflicting financial interests in PHS-funded research, including a requirement for submission of, or review on site, all records pertinent to compliance with this subpart. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records and/or other information that may be available, the PHS Awarding Component may decide that a particular conflict of interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that the Institution has not managed, reduced, or eliminated the conflict of interest in accordance with this subpart. The PHS Awarding Component may determine that suspension of funding under 45 CFR 74.62 is necessary until the matter is resolved.

(c) In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment

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has been designed, conducted, or reported by an Investigator with a conflicting interest that was not disclosed or managed as required by this subpart, the Institution must require the Investigator(s) involved to disclose the conflicting interest in each public presentation of the results of the research.

§ 50.607 Other HHS regulations that apply.

Several other regulations and policies apply to this subpart.

They include, but are not necessarily limited to:

- 42 CFR part 50, subpart D—Public Health Service grant appeals procedure
- 45 CFR part 16—Procedures of the Departmental Grant Appeals Board
- 45 CFR part 74—Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Non-Profit Organizations, and Commercial Organizations; and Certain Grants and Agreements with States, Local Governments and Indian Tribal Governments
- 45 CFR part 76—Government-wide debarment and suspension (non-procurement)
- 45 CFR part 79—Program Fraud Civil Remedies
- 45 CFR part 92—Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments

PART 51—REQUIREMENTS APPLICABLE TO THE PROTECTION AND ADVOCACY FOR INDIVIDUALS WITH MENTAL ILLNESS PROGRAM

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AUTHORITY: 42 U.S.C. 10801, *et seq.*

SOURCE: 63 FR 53564, Oct. 15, 1997, unless otherwise noted.

§ 51.1 Scope.

The provisions of this part apply to recipients of Federal assistance under the Protection and Advocacy for Mentally Ill Individuals Act of 1986, as amended.

§ 51.2 Definitions.

In addition to the definitions in section 102 of the Act, as amended, the following definitions apply:

Abuse means any act or failure to act by an employee of a facility rendering care or treatment which was performed, or which was failed to be performed, knowingly, recklessly, or intentionally, and which caused, or may have caused, injury or death to an individual with mental illness, and includes but is not limited to acts such as: rape or sexual assault; striking; the use of excessive force when placing an individual with mental illness in bodily restraints; the use of bodily or chemical restraints which is not in compliance with Federal and State laws and regulations; verbal, nonverbal, mental and emotional harassment; and any other practice which is likely to cause immediate physical or psychological harm or result in long-term harm if such practices continue.