

§ 94.5

§ 94.5 Management of conflicting interests.

(a) The designated official(s) must: Review all financial disclosures; and determine whether a conflict of interest exists, and is so, 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 the 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.

[60 FR 35817, July 11, 1995; 60 FR 39077, July 31, 1995]

§ 94.6 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

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actions regarding conflicting financial interests in PHS-funded research, including a review of all records pertinent to compliance with this part. HHS may require submission of the records or review them on site. 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 part. The issuance of a Stop Work Order by the Contracting Officer may be 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 has been designed, conducted, or reported by an Investigator with a conflicting interest that was not disclosed or managed as required by this part, the Institution must require disclosure of the conflicting interest in each public presentation of the results of the research.

[60 FR 35817, July 11, 1995; 60 FR 39077, July 31, 1995]

PART 95—GENERAL ADMINISTRATION—GRANT PROGRAMS (PUBLIC ASSISTANCE, MEDICAL ASSISTANCE AND STATE CHILDREN'S HEALTH INSURANCE PROGRAMS)

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