

STANDARD I-6 The organization has and follows written policies and procedures to ensure that research is conducted so that financial conflicts of interest are identified, managed, and minimized or eliminated.

ELEMENT I.6.A. The organization has and follows written policies and procedures to identify, manage, and minimize or eliminate financial conflicts of interest of the organization that could influence the conduct of the research or the integrity of the Human Research Protection Program.

COMMENTARY

An organization that conducts or reviews research involving human participants has an obligation to protect the rights and welfare of participants, ensure the integrity of the research, and ensure the credibility of the HRPP.

An organization or key organizational leaders sometimes have financial interests that conflict with the organization's obligation to protect participants, preserve the integrity of the research, or maintain the credibility of the HRPP. For example, an organization or key organizational leader

might have a proprietary or ownership interest in research that is being reviewed or conducted by the organization. The fact that a financial interest exists does not necessarily indicate that an organization will act contrary to the best interests of research participants. Policies and procedures should describe the process the organization uses to identify, evaluate, manage, and minimize or eliminate such interests.

REGULATORY AND GUIDANCE REFERENCES

- **VA:** VVHA Standards of Ethical Conduct for Employees of the Executive Branch

REQUIRED WRITTEN MATERIALS

(1) Essential requirements:

- (a) Policies and procedures provide a definition of organizational financial conflict of interest that includes:
 - (i) Licensing, technology transfer, patents.
 - (ii) Investments of the organization.
 - (iii) Gifts to the organization when the donor has an interest in the research.
 - (iv) Financial interests of senior administrators.
 - (v) Other financial interests.
- (b) Policies and procedures describe the process to identify or disclose financial conflicts of interest of the organization:
 - (i) A policy addressing financial conflict of interest pertaining to technology transfer and patents is not required if this matter is addressed in other policies and procedures.
 - (ii) A separate policy addressing the identification and management of financial conflicts of interest of senior administrative officials is not required, if this is covered in the organization's financial conflict of interest policy for individuals.
- (c) Policies and procedures describe the committee or individual(s) and process that the organization uses to evaluate and manage organizational financial conflict of interest.
 - (i) Policies and procedure include examples of management strategies.

COMMON TYPES OF MATERIALS THAT MAY BE USED TO MEET THE ELEMENT

- Compliance plans
- Audits, surveys, or data collection tools
- Surveys
- Evaluation reports

OUTCOMES

- The Organization follows policies and procedures for recognizing and managing organizational financial conflicts of interest.
- Financial conflicts of interest are identified, managed, and minimized or eliminated to maintain protection of research participants, ensure the integrity of the research, and ensure the credibility of the HRPP.