

**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.**

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.

**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.

**ELEMENT I.6.B.: The organization has and follows written policies and procedures to identify, manage, and minimize or eliminate individual financial conflicts of interest of Researchers and research staff that could influence the conduct of the research or the integrity of the Human Research Protection Program. The organization works with the Institutional Review Board or Ethics Committee in ensuring that financial conflicts of interest are managed and minimized or eliminated, when appropriate.**

A financial conflict of interest of a researcher or research staff (defined as anyone involved in the design, conduct, or reporting of research) can be broadly defined as an interest that competes with the researcher's or research staff's obligation to

protect the rights and welfare of research participants, preserve the integrity of the research, or uphold the credibility of the HRPP.

Processes to define financial conflict of interest are generally dictated by laws or regulations, and generally vary in terms of what financial interests must be disclosed and when a financial interest is considered a financial conflict of interest. For example, DHHS regulations refer to significant financial interests whereas other laws and codes of conduct for clinical trials do not reference significant financial interests. Further, laws and regulations vary on their requirements regarding managing and reporting financial conflicts of interests, and enforcement of these procedures and education.

An organization should have a policy and procedure to manage or eliminate the financial conflicts of interest of researchers and research staff that meets the laws, regulations, and codes to which it is bound. They should address the primary components of disclosure (what financial interests must be reported and by whom), evaluation and management, monitoring and enforcement, and reporting, and education. Policy and procedures should be consistent but may vary to meet unique requirements of a particular law, regulations, or code when an organization must follow multiple laws, regulations, or codes.

### **Required written materials**

- 1) Essential requirements:
  - a) Policies and procedures define the financial interests of researchers and research staff for which the organization requires disclosure.
  - b) Policies and procedures require disclosure of:
    - i) Financial interests of researchers and research staff.
      - (1) Policies and procedure define the individuals who must disclose financial interests.
      - (2) Financial interests of immediate family members.
    - ii) Financial interests of immediate family members.
      - (1) Policies and procedures define immediate family members.
      - (2) Immediate family members at a minimum include the spouse and each dependent child.
  - c) Policies and procedures describe the process and requirements to educate researchers and research staff about disclosures and responsibilities related to financial conflict of interest.
    - i) Education is required of each individual initially and at least every four years.
    - ii) Education is required immediately when:

- (1) Financial conflict of interest policies are revised in a manner that changes researcher requirements.
  - (2) A researcher is new to the organization.
  - (3) A researcher is non-compliant with financial conflict of interest policies and procedures.
- d) Policies and procedures describe the process the organization uses to obtain financial disclosures from researchers and research staff.
  - i) Minimum of annual disclosure.
  - ii) Update new significant financial interests within 30 days of acquisition or discovery.
- e) Policies and procedures describe the process the organization uses to evaluate and manage financial interests:
  - i) The organizational official(s) or committee designated to evaluate and manage.
  - ii) The definition of significant financial interest.
    - (1) The definition of significant financial interests also defines when a financial interest is related to the research.
    - (2) Designation of the individual or entity that determines relatedness.
- f) Policies and procedures include examples of strategies to manage financial conflicts of interests.
- g) Policies and procedures establish monitoring and enforcement mechanisms for management plans and provide employee sanctions or other administrative actions to ensure researcher compliance.
  - i) Policies and procedures include examples of sanctions or other administrative actions.
  - ii) Management must include the authority to conduct a retrospective review and a mitigation report if necessary.
- h) If a committee or individual other than the IRB or EC evaluates and manages financial interests of researchers and research staff, policies and procedures describe:
  - i) The process to inform the IRB or EC of the results of this evaluation, including any management plan.
  - ii) The process that allows the IRB or EC to have the final authority to decide whether the interest and its management, if any, allows the research to be approved.
- i) Policies and procedures ensure that reporting requirements for funding or regulatory agencies are met.

- j) Policies and procedures have the organization maintain records related to disclosures and management of financial conflicts of interest for at least three years from completion of the research.
- 2) When following PHS requirements:
    - a) Policies and procedures describe the process the organization uses to obtain disclosures from researchers and research staff of institutional responsibilities related to significant financial interests.
      - i) Policies and procedures define institutional responsibilities.
    - b) Policies and procedures describe the process the organization uses to obtain disclosures from researchers and research staff of reimbursed or sponsored travel related to institutional responsibilities.
    - c) Policies and procedures define what reimbursed or sponsored travel is required to be reported.
      - i) At a minimum, travel disclosures will include the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration.
- 3) When following VA requirements:
    - a) VA facilities
      - i) VA facilities are not required to follow PHS requirements, even when research is funded by a PHS agency (e.g., NIH). The PHS requirements do not apply to the VHA. Although the PHS requirements state they are applicable to “each institution that is applying for, or that receives, PHS research funding ...,” (42 CFR 50.601), the definition of “institution” excludes federal agencies (42 CFR 50.603).] PHS requirements are found at 42 CFR 50.601-607 (especially 42 CFR 50.604, “Responsibilities of Institutions Regarding Investigator Financial Conflicts of Interest”).

### **Common types of materials that may be used to meet the element**

- Financial disclosure form
- Organizational policy and procedure on researcher conflict of interest
- Reviewer checklist

### **Outcomes**

- Conflicts of interest are identified, managed, and minimized to maintain protections of participants, ensure the integrity of research, and ensure the credibility of the HRPP.

- Management plans are monitored and enforced and when necessary, non-compliance is addressed with sanctions or administrative actions.
- Conflicts of interest are reported to regulatory agencies when required by policies and procedures.