



Tip Sheet 10: Financial Conflict of Interest for Researchers and Research Staff

Related Accreditation Elements: I.6.B. and III.1.B.

Organizations should have policies and procedures that ensure financial conflicts of interest of Researchers and Research Staff (defined as anyone responsible for the design, conduct, or report of research) do not adversely affect the protection of participants, the integrity of the research, or the credibility of the Human Research Protection Program. Processes to define financial conflict of interest are generally dictated by laws, regulations, and codes, and generally vary in terms of what financial interests must be disclosed and when a financial interest is considered a financial conflict of interest. Organizations should have policies and procedures to manage or eliminate the financial conflicts of interest of Researchers and Research Staff that meet the laws, regulations, and codes to which they are bound. They should address the primary components of disclosure of financial interests, evaluation of disclosed financial interests to determine which ones are financial conflicts of interest, management of those considered to be financial conflicts of interest, monitoring and enforcement of policies, reporting, and education. Policies and procedures should be consistent but may vary to meet unique requirements of a particular law, regulation, or code when an Organization must follow multiple laws, regulations, and codes. Organizations may use personnel and committees external to the IRB or EC to evaluate and manage financial conflicts of interest. However, policies and procedures must provide that the IRB or EC make final determinations that participants are protected.

Please note:

The first step is to determine which laws, regulations, and codes your Organization or Researchers must follow. Laws, regulations, and codes vary considerably with respect to defining a financial conflict of interest. Thus, disclosure thresholds for reporting financial interests should be carefully chosen to ensure that financial conflicts of interest are appropriately reported to regulatory agencies. Some regulations are broad (e.g., Food and Drug Administration (FDA) regulations); whereas others are detailed and encompass many responsibilities required of institutions (e.g., Department of Health and Human Services (HHS) regulations).

Your Organization may impose a lower threshold than the minimum requirement by applicable laws and regulations for Researchers and Research Staff to disclose financial interests.

While Organizations should develop policies and procedures that are consistent, they are cautioned not to apply a law or regulation to all research or all financial disclosures without understanding the consequences of that policy decision. For example, if an Organization decides to apply the HHS regulation to all research, it might allow the agency enforcing the regulation to inspect all research even those research studies that are not sponsored by HHS.

Recommended Content:

- 1. Cite or repeat the laws or regulations related to financial conflict of interest that your Organization must follow.**
- 2. Define the individuals who are covered by the financial conflict of interest policy.**
 - Include in the definition Researchers and other Research Staff and their immediate family members (At a minimum, family members include spouses and dependent children).

- When following the HHS regulation, the definition must include institutional responsibilities that trigger disclosing financial interests.
- 3. Define the financial interests that must be disclosed:**
- Include in the definition aggregate financial interests of Researchers and Research Staff and their immediate family members.
 - Include financial criteria in the definition that are consistent with the laws, regulations, and codes your Organization or Researchers and Research Staff must follow.
 - When following the HHS regulation, reimbursed or sponsored travel that must be disclosed is defined along with the information about the travel that must be disclosed.
 - a. At a minimum, the purpose of the trip, the identity of the sponsor, the destination, and the duration of the trip must be disclosed.
 - b. Define the criteria when the entity reviewing such travel will request additional information.
 - The threshold for disclosing financial interests should not vary. When a threshold varies (for example, limiting the disclosure of reimbursed or sponsored travel related to institutional responsibilities to HHS-sponsored research), mechanisms must be in place so that the Organization is able to apply legal or regulatory requirements appropriately.
- 4. Education**
- Policies and procedures describe the process and requirements to educate Researchers and Research Staff about disclosures and responsibilities related to financial conflict of interest.
 - a. Education is required of each individual initially at least every four years.
 - b. Education is required immediately when:
 - Financial conflict of interest policies are revised in a manner that changes researcher requirements.
 - A researcher is new to the organization.
 - A researcher is non-compliant with financial conflict of interest policies and procedures.
 - Develop supporting documents, guidelines, and training materials.
- 5. Describe the process to disclose financial interests:**
- Describe the process for disclosure, such as completion of a financial statement.
 - Describe the events at which disclosure must be made, such as:
 - At least annually.
 - When there are changes in financial circumstances.
 - Describe to whom financial interests are disclosed.
- 6. Describe the time frame for reporting changes in financial interests related to approved research.**
- 7. Describe the process used to evaluate and, when necessary, to manage financial conflicts of interest:**
- Define a significant financial interest and define when a significant financial interest meets the definition of a financial conflict of interest as stipulated in applicable laws, regulations, or codes.
 - a) Include in the definition of financial conflict of interest: Related to the specific research study.
 - b) For HHS-sponsored research, include a description of institutional responsibilities.
 - Identify the entity that determines whether a financial interest is significant and if so, whether it constitutes a financial conflict of interest.
 - Identify the entity that judges whether financial conflicts of interest require management.

- Describe the criteria used to determine whether financial conflicts of interest require management. At a minimum, the criteria must include:
 - Whether the financial conflict of interest will adversely affect the protection of participants in terms of the criteria for IRB or EC approval.
 - Whether the financial conflict of interest will adversely affect the integrity of the research.
 - Describe the options considered for managing financial conflicts of interest.
 - Identify the entity that selects the management plan.
 - Identify the entity that determines that the management plan is adequate.
 - Describe the criteria used to determine that the management plan is adequate.
 - Describe how the evaluation and management plan of a financial conflict of interest is documented.
- 8. Describe the process used to monitor and enforce management plans and provide employee sanctions or other administrative actions to ensure research compliance.**
- Identify the entity that monitors management plans and the process used for monitoring.
 - Identify the entity designated, and the process used, to enforce management plans and implement sanctions or other administrative actions, when necessary.
 - a) Provide examples of sanctions and other administrative actions.
 - Describe to which research monitoring and enforcement activities will be applied.
- 9. Describe the role of the IRB or EC:**
- Indicate that financial interests are evaluated and managed prior to IRB or EC approval.
 - If the evaluation and management of financial interests are not performed by the IRB or EC:
 - Describe the process to communicate the information regarding the management plan to the IRB or EC when there is a financial conflict of interest.
 - Indicate that the information communicated to the IRB or EC is used by the IRB or EC in the review process.
 - Describe the actions the IRB or EC may take when evaluating a management plan.
 - Describe the process so that the IRB or EC has the final authority to determine whether the research in which the researcher has a financial conflict of interest and the management plan of that conflict, if any, allow the research to be approved.
- 10. Describe how reporting requirements are completed.**
- Indicate the entity that is responsible for fulfilling reporting requirements.
 - Describe the internal reporting requirements.
 - Describe the external reporting requirements to funding or regulatory agencies.
- 11. Record Keeping**
- 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.

Applicable U.S. Regulations or Requirements

Definitions of, management, and reporting requirements for financial conflicts of interest differ for the three U.S. federal agencies (FDA, HHS, and National Science Foundation) that have financial conflict of interest requirements related to sponsored or regulated research. Review the specific requirements in each regulation that applies to your Organization. Differences among the agency requirement include definition of financial conflict of interest, management of financial conflict of interest, and enforcement, education, and reporting requirements.