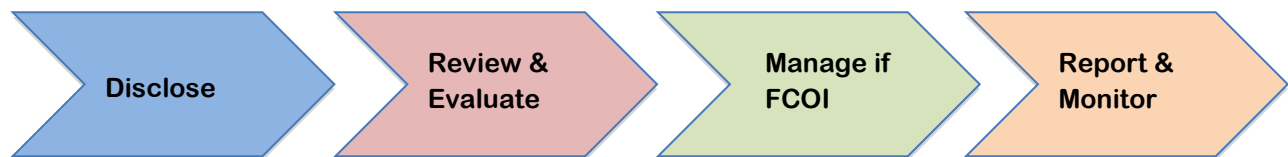


FINANCIAL CONFLICTS OF INTEREST IN RESEARCH GUIDANCE FOR INSTITUTIONAL OFFICIALS

Overview

Institutional compliance with Federal (42 CFR Part 50 Subpart F) and University (AR 7:2) regulations governing financial conflicts of interest in research typically involves four steps.



First, the Investigator discloses those significant financial interests that reasonably appear related to his/her institutional responsibilities. Second, the Institutional Official or designee reviews the Disclosure Statement to evaluate whether a disclosed significant financial interest is related to the Investigator's research and, if so related, whether there appears to be a financial conflict of interest. If there does appear to be a financial conflict of interest, the case is referred to the Research Conflict of Interest Committee, which makes recommendations to the Institutional Official regarding the management, reduction, or elimination of the conflict. Finally, the Institutional Official fulfills sponsoring agency reporting requirements and monitors Investigator adherence to an implemented management plan.

In accordance with 42 CFR §50.604(f) and AR 7:2, this document provides guidance to assist the designated Institutional Official or designee (hereafter "Reviewer") in completing the second step of the process. The Reviewer is expected to be thoroughly familiar with the requirements of both 42 CFR Part 50 and AR 7:2.

Conflict of Interest

A conflict of interest is a set of circumstances that creates a risk that one's professional judgment or actions regarding a primary interest (e.g., the integrity of research, the welfare of human research subjects) will be unduly influenced by a secondary interest (e.g., financial gain, other personal interest). A financial conflict of interest as used in the regulations means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.

The University encourages its members to engage in outside activities and relationships that enhance its missions. Conflicts of interest are a natural outcome of successful research and commercialization activities. It is important for Reviewers to understand that the mere existence of a conflict of interest does not mean that an actual incident of bias has occurred or that an individual has done something wrong. But to preserve the public trust the University must be able to make informed judgments about such activities and require appropriate management, reduction or elimination of conflicts of interest.

Reviewing Disclosure Statements

After an Investigator completes a new Disclosure Statement or updates an existing disclosure, it must be reviewed within 60 days by a designated Reviewer. If the Investigator discloses no significant financial interests, no further action is required by the Reviewer other than to document that the Disclosure Statement review has been completed.

If the Investigator discloses one or more significant financial interests, there are two principal steps involved in evaluating the disclosure. The first involves an Institutional determination of relatedness – whether a disclosed significant financial interest is related to the Investigator’s research. If it is determined to be related, the second step is to determine whether or not it constitutes a financial conflict of interest.

Relatedness: An Investigator’s significant financial interest is related to research if that significant financial interest could be affected by the research or is an entity whose financial interest could be affected by the research.

A key difference between the earlier (1995) and the new Final Rule at 42 CFR Part 50 is the shift of responsibility from the Investigator to the Institution in determining relatedness. This is especially critical, if the research is supported by a PHS awarding component (e.g., NIH, CDC, FDA). The Institution may involve the Investigator in this process; but responsibility for a final determination of relatedness rests with the Institutional Official.

The Disclosure Statement asks the Investigator to explain how the involvement with an outside entity reasonably appears related to his/her institutional responsibilities. It also asks if the outside entity sponsors the Investigator’s research. We can anticipate that most Investigators will accurately describe that relatedness, especially as it relates to their research responsibilities. The Reviewer can accept such a declaration of relatedness. In that case, the relatedness is documented and the Reviewer moves on to determining whether or not the significant financial interest is a financial conflict of interest.

If the Investigator discloses a significant financial interest but claims that it is not related to his/her research, additional diligence is required on the part of the Reviewer. He/she must then carefully compare information about the significant financial interest to the list of active and pending sponsored projects, paying particular attention to any active or pending PHS supported projects. If the Reviewer is unable to readily make the relatedness determination, he/she may contact the Investigator to ask clarifying questions.

Ultimately, it may be necessary to make a judgment call about relatedness. In that case, the Reviewer should err on the side of assuming relatedness unless there is clear evidence to the

contrary. This is because many cases in which the significant financial interest is related to research will not rise to the level of a financial conflict of interest.

Financial Conflict of Interest: A financial conflict of interest exists when the significant financial interest could directly and significantly affect the design, conduct or reporting of the research. Again, this especially applies to PHS-funded research as required at 42 CFR §50.604(f).

There are several factors to consider when evaluating whether there appears to be financial conflict of interest. Among them are:

A. What is the nature of the research?

It is of a basic or fundamental nature directed at understanding basic scientific processes?

Is the degree of replication and verification of results of the research such that immediate commercialization or clinical application is unlikely?

Is the goal of the research to evaluate an invention or technology that is linked to the significant financial interest? For example, is the significant financial interest a patent or financial interest in a company that has licensed an invention or technology?

Is the goal of the research a comparative evaluation of a technology or process in which the Investigator has a significant financial interest? That is, could the outcome of the research, whether positive or negative, impact the value of the Investigator's significant financial interest? What does the Investigator stand to win or lose?

B. Does the research involve human subjects?

Is the project a clinical trial? If so, what phase is it?

Are there double-blind conditions or the involvement of a data and safety monitoring board?

If the Investigator or the University has an intellectual property interest, has the rebuttable presumption against conducting the research at UK been adequately addressed?

C. What is the role of the individual on the research project?

Does the Investigator have an opportunity to bias the results?

Is there sufficient independent review of the research conducted and the reporting of research results to mitigate any undue bias?

What is the magnitude of the significant financial interest (e.g., the amount of consulting, the percentage or value of equity interests)?

D. What is the source of funding for the research?

Does the Investigator's significant financial interest involve the sponsor of the research?

Is that sponsor a licensee of technology developed by the Investigator?

If so, what has been the amount of licensing payments received to date by the Investigator or is anticipated in the future?

E. Does the significant financial interest involve a privately held company (i.e., not publicly traded)?

Could the Investigator's significant financial interest allow the Investigator to have influence over company decisions?

Could the outcome of the research have a significant impact on the company's business or financial outlook?

How likely is the Investigator likely to profit from such an impact?

F. What is the nature of the relationship between the Investigator and the entity?

Does the Investigator have a leadership and/or decision-making role in the entity?

Are there close ties (i.e., scientific advisory board) or a more impersonal relationship (e.g., ownership of stock in a publicly-traded entity)?

What is the number and nature of relationships between the Investigator and the entity?

Multiple entanglements can create a relationship with an outside entity that is stronger than the sum of its parts.

G. Has the Investigator disclosed sponsored or reimbursed travel (PHS Investigators only)?

What is the identity and type of sponsor of that travel? (i.e., for-profit versus non-profit)

Does that entity also sponsor the Investigator's research?

Note to Reviewer: In making this evaluation, you are not expected to make a judgment about the Investigator's motives, intentions, or personal character.

If the answers to these questions lead the Reviewer to conclude that there appears to be a financial conflict of interest, the Reviewer will consult with the Institutional Official. If a financial conflict of interest appears to exist, the Institutional Official will assign a financial conflict of interest case number (FCOI) and follow procedures outlined in AR 7:2, Sections VIII and IX.

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