

CONFLICTS OF INTEREST

Certain federal agencies, including the Public Health Service (“PHS”) and the National Science Foundation (“NSF”), impose conflict of interest requirements on institutions that apply for funding as well as on the investigators who would participate in the federally-sponsored research or educational activities.

PHS and NSF mandate that, by the time an application for funding is submitted to the relevant agency, all “Investigators” who plan to participate in the proposed research or educational activities must have disclosed to a designated institutional official any “Significant Financial Interests” (a) that would “reasonably appear to be affected by” the research or educational activities “for which [PHS/NSF] funding is sought”; and (b) in “entities whose financial interests would reasonably appear to be affected by” the research or educational activities.

An “*Investigator*” is anyone “responsible for the design, conduct, or reporting” of research or educational activities funded by or proposed for funding by PHS or NSF. For purposes of disclosing Significant Financial Interests, the term “Investigator” includes the individual’s spouse and dependent children.

A “*Significant Financial Interest*” is, generally speaking, “anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).” There are certain exemptions (such as “[s]alary, royalties, or other remuneration from the applicant institution”) and the following threshold levels apply in determining whether a financial interest is significant: (a) An equity interest must be worth over \$10,000 and/or “represent more than a five percent ownership interest in any single entity”; and (b) “Salary, royalties or other payments” must be expected to reach over \$10,000 across the next twelve months.

During the period of an award, Investigators’ disclosures must be updated once per year “or as new reportable Significant Financial Interests are obtained.” The designated official at an institution is required to request and review disclosures, and to determine if a conflict of interest exists (i.e. determine if “a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting” of the research or educational activities). If the designated official identifies a conflict of interest, he or she must decide what steps the institution should take to “manage, reduce or eliminate” the conflict of interest. PHS and NSF offer examples of the kinds of management techniques that institutions may employ (for instance, monitoring by “independent reviewers,” amendment of the research plan, and “[d]ivestiture of Significant Financial Interests”). In addition to managing, reducing or eliminating a conflict of interest, institutions must make certain required reports regarding the existence of a conflict of interest to their funding agencies.

Both PHS and NSF mandate that institutions adopt and enforce conflict of interest policies, which must be consistent with agency requirements. In some cases, institutions maintain conflict of interest policies that exceed federal requirements and/or that apply beyond federally-sponsored research.

References: The PHS regulations referenced above may be found at 42 C.F.R. part 50, subpart F (grants and cooperative agreements) and 45 C.F.R. part 94 (contracts). NSF’s conflict of interest requirements appear in Section 510 of its Grant Policy Manual, available at http://www.nsf.gov/pubs/manuals/gpm05_131/index.jsp.