

Summary of the Federal Regulations Relating to Financial Conflicts of Interest for PHS (NIH) and NSF Funding Applications

Federal regulations require that all applicants for funding (grant, cooperative agreements, and contracts) from the Public Health Service (PHS/NIH) or from the National Science Foundation (NSF) must “disclose to an official(s) designated by the [applicant] institution a listing of Significant Financial Interests (and those of his/her spouse and dependent children) that would reasonably appear to be affected by research proposed for funding by the PHS [or NSF]. The institutional official(s) will review those disclosures and determine whether any of the reported financial interests could directly and significantly affect the design, conduct, or reporting of the research, and, if so, the institution must, prior to any expenditure of awarded funds, report the existence of such conflicting interests to the PHS Awarding Component and act to protect PHS-funded research from bias due to the conflict of interest” [from *Federal Register* Vol. 60, No. 132, 42 CFR Part 50 Summary].

It must be emphasized that it is the responsibility of the “Investigator” to disclose all “Significant Financial Interests” (see definitions below). It is the responsibility of the designated official of the institution to make the determination as to whether the disclosed Significant Financial Interests constitute a conflict of interest. If the designated institutional official determines that a Significant Financial Interest may “directly and significantly affect the design, conduct, or reporting” of research funded by the PHS or NSF, then a conflict of interest exists and the institution is required to implement procedures to manage, reduce, or eliminate the conflict of interest prior to the institution’s expenditure of any funds under the award.

Definitions (quoted from 42 CFR 50.603)

1. “Investigator” means the principal investigator or any other person who is responsible for the design, conduct, or reporting of research. . . . [In considering financial interests,] “Investigator” includes the Investigator’s spouse and dependent children.
2. “Significant Financial Interest” means anything of monetary value, including but not limited to salary or other payments for service (e.g., consulting fees or honoraria); equity interest (e.g., patents, copyrights, and royalties from such rights). The term [Significant Financial Interest] does not include:
 - (a) salary, royalties, or other remuneration from [Cornell];
 - (b) any ownership interest in the institution if the institution is an applicant under SBIR [Small Business Innovation Research] Program;
 - (c) income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
 - (d) income from service on advising committees or review panels for public or nonprofit entities;
 - (e) an equity interest that when aggregated for the investigator and the investigator’s spouse and dependent children, meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measure of fair market value, and does not represent more than a five percent ownership interest in any single entity; or
 - (f) salary, royalties, or other payments that when aggregated for the investigator and the investigator’s spouse and dependent children over the next twelve months are not expected to exceed \$10,000.