

SUMMARY & DEFINITIONS

Summary

The 2011 revised regulation includes comprehensive changes, focusing on these areas:

1. Definition of Significant Financial Interest
2. Extent of Investigators' disclosure of information to Institutions regarding their Significant Financial Interests;
3. Institutions' management of identified Financial Conflicts of Interest
4. Information reported to the PHS funding component (e.g., NIH);
5. Information made accessible to the public (i.e., Institutional FCOI policy and FCOIs of senior/key personnel); and
6. Investigator training.

An institution applying for or receiving PHS funding from a grant, cooperative agreement, or contract that is covered by this rule must be in full compliance with all of the regulatory requirements no later than August 24, 2012; and immediately upon making its institutional Financial Conflict of Interest policy publicly accessible.

Definitions (changes in red)

Investigator – Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research proposed for funding by the NIH, including collaborators or consultants.

Institutional Responsibilities – an Investigator's professional responsibilities on behalf of the Institution, which may include research, teaching, consultation, professional practice, institutional committee memberships, and service on panels such as IRBs or Data Safety Monitoring Boards.

Remuneration – salary, consulting fees, honoraria, paid authorship (**excludes** income from seminars, lectures, or teaching engagements sponsored by federal, state or local government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with institutions of higher education.

Equity Interest - stock, stock options, or other ownership interest (**excludes** income from investment vehicles such as mutual funds and retirement accounts as long as investigator does not control investment decisions made in these vehicles.)

Intellectual Property Rights and Interests – patents and copyrights (**excludes** IP rights assigned to the Institution and agreements to share royalties related to such rights.)

Significant Financial Interests (SFI) – include financial interests **related to an Investigator's institutional responsibilities**, aggregated for the investigator and those of his/her spouse and dependent children:

1. **SFI in publicly traded entities** – the value of remuneration in the **12 months preceding disclosure** and the value of any equity interest as of the date of disclosure that, when aggregated, exceeds **\$5,000**.
2. **SFI in non-publicly traded entities** - the value of remuneration in the **12 months preceding disclosure** exceeding **\$5,000**; or **ANY equity interest or intellectual property rights and interests**, upon receipt of income related to such rights and interests.
3. **Reimbursed or sponsored travel** - travel paid on behalf of the investigator and not reimbursed directly to investigator so that the exact monetary value may not be readily available. This does not include travel on sponsored projects if charged to a grant account or payment for travel for seminars, lectures, teaching, or service on advisory or review panels for government agencies or institutions of higher education (IHE) or facilities affiliated with IHEs.

Financial Conflict of Interest (FCOI) – A significant financial interest that could directly and significantly affect the design, conduct, or reporting of the research.

All Significant Financial Interests that meet the above thresholds must be disclosed. The institution will determine if the SFI represents a Financial Conflict of Interest with the research project submitted for NIH funding.