Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought

And Responsible Prospective Contractors

Final Rule

The U.S. Department of Health and Human Services is committed to preserving the public trust in the objectivity of biomedical and behavioral research. We at the National Institutes of Health strongly believe that it is vital that all research be conducted with the highest scientific and ethical standards. In 1995, HHS promulgated the current Public Health Service (PHS) regulations, ``Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought'' and ``Responsible Prospective Contractors.'' These are also known as the financial conflict of interest, or FCOI, regulations (42 CFR Part 50 Subpart F and 45 CFR Part 94).

In the intervening years, biomedical and behavioral research and the resulting interactions among government, research institutions, and the private sector has become increasing complex. This complexity, as well as increased public scrutiny and a need to strengthen transparency and accountability have led HHS to propose a more rigorous approach to Investigator disclosure, management of financial conflicts, and federal oversight.

To that end, after reviewing public comments from HHS' advance notice of proposed rulemaking (ANPRM) published on May 8, 2009, HHS published a notice of proposed rulemaking (NPRM) on May 21, 2010. The proposed rule was published to amend the 1995 regulations by expanding and adding transparency to investigators' disclosure of significant financial interests, enhancing regulatory compliance and effective institutional oversight and management of investigators' financial conflicts of interests, as well as HHS' compliance oversight.

After careful consideration of the comments to the NPRM, HHS is publishing a final rule (http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf) that amends the 1995 regulations. Major changes to the 1995 regulations include:

- Lower financial disclosure thresholds
- New conflict of interest training
- New public accessibility requirements
- Increased transparency for travel reimbursement

These changes are outlined further in the attached table.

Major Changes to the 1995 Regulations

Topic	1995 Regulations	2011 Final Rule
Significant Financial Interests (SFI) threshold	De minimis threshold of $10,000 for disclosure generally applies to payments or equity interests	De minimis threshold of $5,000 for disclosure generally applies to payments for services and equity interests. Includes any equity interest in non-publicly traded entities.
Which SFIs need to be disclosed (once the threshold is met)	Only those SFI the Investigator deems related to the PHS-funded research.	All SFI related to the Investigator's institutional responsibilities.
Excluded from disclosure requirement	Income from seminars, lectures, or teaching, and service on advisory committees or review panels, for public or nonprofit entities	Income from seminars, lectures, or teaching engagements sponsored by and service on advisory or review panels for a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
Types of SFI excluded	All forms of remuneration are included – specific questions such as mutual funds and blind trusts are addressed in FAQ on the NIH website.	Excludes income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.
Travel reimbursements and sponsored travel	Travel reimbursement is not mentioned explicitly in the regulations but is not excluded from the SFI definition.	Disclose the occurrence of any reimbursed travel or sponsored travel related to Institutional responsibilities (including purpose of trip, sponsor/organizer, destination, and duration). NOT required to disclose travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The Institution will determine if any travel requires further investigation, including determination or disclosure of the monetary value.
Information on an identified Financial Conflict of Interest (FCOI) reported by the Institution to the PHS Awarding Component	• Grant/Contract number • Project Director/Principal Investigator (PD/PI) or Contact PD/PI • Name of Investigator with FCOI • Whether FCOI was managed, reduced, or eliminated	INITIAL REPORT Requirements in 1995 reg, plus: • Name of the entity with which the Investigator has a FCOI • Nature of FCOI, e.g., equity, consulting fees, travel reimbursement, honoraria • Value of the financial interest $0-4,999; $5K-9,999; $10K-19,999; amts between $20K-$100K by increments of $20K; amts above $100K by increments of $50K or statement that a value cannot be readily determined. • A description how the financial interest relates to PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research

Topic	1995 Regulations	2011 Final Rule
		• Key elements of the Institution's management plan ANNUAL REPORT • Status of the FCOI • Changes to the management plan
Subrecipient Institutions/Investigators and Reporting of identified FCOIs	Institutions must take reasonable steps to ensure that Investigators working for subs comply with the regs by requiring those Investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regs	• Incorporate as part of a written agreement terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or FCOI reporting requirements • Subrecipient Institutions who rely on their FCOI policy must report identified FCOIs to the awardee Institution in sufficient time to allow the awardee Institution to report the FCOI to the PHS Awarding Component (e.g., NIH through the eRA Commons FCOI Module) to meet reporting obligations.
Public Accessibility	No requirement	Make certain information available concerning identified FCOIs held by senior/key personnel via a publicly accessible Web site or by a written response to any requestor within five business days of a request, and update such information as specified in the rule.
FCOI training	No requirement	Each Investigator must complete training prior to engaging in research related to any PHS-funded grant or contract and at least every four years, and immediately under the designated circumstances: • Institutional FCOI policies change in a manner that affects Investigator requirements • An Investigator is new to an Institution • An Institution finds an Investigator noncompliant with Institution's FCOI policy or management plan.
Retrospective Review ("Mitigation plan," discussed in NPRM)	Not mentioned	Institution is required to conduct a retrospective review in those cases of non-compliance with the regulation but is not required to report the review to the PHS Awarding Component. The Institution will be required to notify the PHS Awarding Component promptly and submit a report to the PHS Awarding Component only in cases where bias is found. The report will address the impact of the bias on the research project and the actions the Institution has taken, or will take, to eliminate or mitigate the effect of the bias.