



TITLE:	FCOI (Financial Conflict of Interest)
SUBJECT:	Compliance with DHHS 2011 Rule regarding FCOI Reporting
DOCUMENT TYPE:	
DOCUMENT NUMBER:	

#### PURPOSE

To document and implement Department of Health and Human Services FCOI reporting requirements, according to DHHS 42 CFR Part 50 and DHHS 42 CFR Part 94, as amended by the 2011 Final Rule on the 1995 FCOI regulations.

#### REFERENCE DOCUMENTS

- NIH FCOI Website: <http://grants.nih.gov/grants/policy/coi/index.htm>
- FCOI Training Webinar [http://grants.nih.gov/grants/policy/coi/fcoi\\_webinar\\_for\\_nih\\_grantees.ppt](http://grants.nih.gov/grants/policy/coi/fcoi_webinar_for_nih_grantees.ppt)
- FCOI User Guide [http://era.nih.gov/files/fcoi\\_user\\_guide.pdf](http://era.nih.gov/files/fcoi_user_guide.pdf)
- Department of Health and Human Services 42 CFR Part 50
- Department of Health and Human Services 42 CFR Part 94
- NIH Slides from FCOI Webinar
- Table Chart: Major Changes to 1995 Regulations
- For supplemental information see Department of Veterans Affairs Research Service Policy Memorandum,4/20/11

#### DEFINITIONS

**Financial Interest** – anything of monetary value, whether or not the value is readily available. The financial interests that must be disclosed by the Investigator include the aggregated amounts or values of financial interests held by the Investigator and his/her spouse and dependent children.

**Significant Financial Interest** – compensation or other payment for services, equity interests and intellectual property rights within the Financial Conflict of Interest. 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. Must report all SFI related to the Investigator's institutional responsibilities.

**Exclusions:** Investigator is not required to report 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 by 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. 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:** Investigator must disclose the occurrence of any reimbursed travel or sponsored travel related to institutional responsibilities (including purpose of trip, sponsor/organizer, destination, and duration). Investigator is NOT required to disclose travel that is reimbursed or sponsored by federal, state, or local government agency, and 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 monetary value.

**Financial Conflict of Interest (FCOI)** – when any financial arrangement, situation or action affects or is perceived to exert inappropriate influence on the design, review, conduct, results or reporting of research findings.

**Public Health Service (PHS) Awarding Component** – the organizational unit of the PHS that funds the research that is subject to promoting objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of an Investigator.

**42 CFR Part 50 – Subpart F:** Responsibility of applicants for promoting objectivity in research for which Public Health Service funding is sought.

**42 CFR Part 94 – Responsible Prospective Contractors:** promotes objectivity by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research performed under PHS contracts will be free from bias resulting from Investigator Financial Conflict of Interest.

## FCOI REPORT REQUIREMENTS

Report must be submitted to the PHS Awarding Component, and must include the following information:

- 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
- 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; amounts between \$20K-\$100K by increments of \$20K; amounts above \$100K by increments of \$50K or statement that a value cannot be readily determined
- A description of 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
- Key elements of the Institution's Management Plan: Annual Report, status of the FCOI, changes to the Management Plan
- After a "new" FCOI is reported, the Institution is responsible to submit an "annual" report each subsequent year during the project's competitive segment (see details below).

## RESPONSIBILITY OF PRIME ENTITY TO MONITOR SUBRECIPIENTS

Institutions must incorporate as part of a written agreement terms that establish whether the FCOI policy of the awardee Institution or the policy of the subrecipient will apply to subrecipient investigators, and must include time periods to meet disclosure and/or FCOI reporting requirements. Subrecipient Institutions who rely on their own 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**

Awardee institution must make available certain information concerning identified FCOIs held by senior/key personnel. Notification may be accomplished via a publicly accessible Web site (such as that established by eRA Commons for the purpose) or by a written response to any requestor within five business days of a request. Information must be regularly updated as specified in the rule.

## **FCOI TRAINING**

Each Investigator must complete training immediately upon joining the Institution, and immediately when the Institution's FCOI policy changes in a manner that affects investigator requirements. Each investigator must review prior to engaging in research related to any PHS-funded grant or contract, or at least every four years.

## **RETROSPECTIVE REVIEW—EXISTING BUT UNREPORTED FCOI**

If an existing but previously unidentified or unreported FCOI is determined, the Institution is required to conduct a retrospective review but is not required to report the review to the PHS Awarding Component unless bias is determined. Where bias is found, the Institution must notify the PHS Awarding Component promptly and submit a report to the PHS Awarding Component. 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.

## **ANNUAL REPORT**

After a "new" FCOI is reported, the Institution is responsible to submit an "annual" report each subsequent year during the project's competitive segment. The annual FCOI report will address the status of the financial interest and any changes to the management plan. Annual FCOI reports shall address whether the FCOI is still being managed or explain why the FCOI no longer exists. Annual FCOI reports must be submitted through the eRA Commons FCOI Module at the same time as when the Institution is required to submit the annual progress report (i.e., two months prior to the start date or 45 days prior to the start date of the noncompeting continuation award), including a multi-year funded progress report, or at the time of the extension (e.g., submission of an extension notification in the eRA Commons or submission of a NIH prior approval request, whichever is applicable.)