



What You Need to Know About Financial Conflict of Interest

Presented by:
Office of Sponsored Programs



What is FCOI reporting?

- ❖ A form of reporting required by federal agencies for investigators working on sponsored projects.
- ❖ FCOI reporting certifies that either
 - ❖ (A) an investigator has no conflicts of interest, or
 - ❖ (B) an investigator has financial interests that could constitute conflict of interest in relation to federally-funded research, and has developed an appropriate plan to monitor and manage such conflicts.

What's the concern?

- ❖ We are obligated by federal regulations to certify FCOIs.
- ❖ Report requirements vary from one agency or program to another.
- ❖ Erroneous certifications (accidentally or with intent)
 - ❖ Can be viewed as fraud
 - ❖ May lead to an institutional audit
 - ❖ May result in significant penalties.

Audits are becoming increasingly common.
Preliminary results from our August 2012 audit indicate no serious findings; new PHS regulations demand FCOI monitoring.

Summary of FCOI regulations

- ❖ NSF and NIH both require reporting.
- ❖ New (2011) regulations went into effect on August 24, 2012 (or earlier, according to date of posting by C of I) for new grants from DHHS (NIH, in particular).
- ❖ In the meantime, the 1995 NIH rules are in effect for INBRE and other active NIH awards.
- ❖ Significant changes in the 2011 regulations, including training, apply to our current INBRE award at the next noncompetitive renewal, or whenever any investigator applies for new funding after 8.24.2012.

NSF regulations

For NSF-funded projects,

- ❖ Each grantee institution employing more than 50 persons must maintain an appropriate written and enforced policy on conflict of interest.
- ❖ Conflict of interest policy must require that each investigator disclose to a responsible representative of the institution all **significant financial interests** of the **investigator** (including the investigator's spouse and dependent children)
 - ❖ (i) that would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF; or
 - ❖ (ii) in entities whose financial interests would reasonably appear to be affected by such activities.

NSF regulations, cont'd

... definitions for NSF-funded work

- ❖ “Investigator” means the PI, co-PIs, and any other person at the institution who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by NSF
- ❖ “Significant financial interest” means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights), excluding the following:

NSF regulations, cont'd

... exclusions for NSF-SFIs. The term does not include:

- ❖ Income from the applicant institution (College of Idaho);
- ❖ Any ownership interests under the SBIR or STTR programs;
- ❖ Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
- ❖ Income from service on advisory committees or review panels for public or nonprofit entities;
- ❖ Equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children, (1) does not exceed \$10,000 in value AND (2) does not represent more than a 5% ownership interest in any single entity; or
- ❖ Aggregated salary, royalties or other payments that are not expected to exceed \$10,000 during a 12-month period.

NSF regulations, cont'd ... other rules:

- ❖ Investigators must provide all required financial disclosures at the time the proposal is submitted to NSF. Financial disclosures must be updated during the period of the award, either annually, or as new reportable SFIs are obtained.
- ❖ Must designate one or more persons to review financial disclosures, determine whether a conflict of interest exists, and determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce or eliminate such conflict of interest: when the reviewer(s) reasonably determines that an SFI could directly and significantly affect the design, conduct, or reporting of NSF-funded research or educational activities. At C of I, the VPAA is responsible.
- ❖ Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate conflicts of interest.

NSF regulations summary:

- ❖ “Investigator,” “SFI” defined: Includes spouse & children; \$10,000 de minimis standard, with exclusions.
- ❖ Must disclose at time of proposal submission, annually during award, or when SFIs change.
- ❖ Upon disclosure, responsible person(s) determine whether a conflict of interest exists, and determine measures, if any, to be imposed by the institution to manage, reduce or eliminate such conflict of interest: when an SFI could directly and significantly affect the design, conduct, or reporting of NSF-funded research or educational activities.
- ❖ No training requirement, no explicit travel reporting.

NIH rules: 1995 vs 2011 regulations

The 2011 NIH rules went into effect 8.24.2012.

- ❖ Apply to grants with NOA date after 8.24.2012.
- ❖ Grants with prior NOA dates are under the 1995 rules.
- ❖ New rules apply to new APPLICATIONS, and non-competing renewals.
- ❖ New training requirement
- ❖ \$5,000 de minimis standard; SFIs cannot be reviewed by PI; sponsored travel reporting; includes ALL institutional work, not just research; includes spouse & dependent children
- ❖ See <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-109.html>

Topic	1995	2011
SFI threshold	\$10,000 [§]	\$5,000* [§]
Which SFIs?	Those deemed by PI to be research-related	All SFIs related to College duties
Sponsored travel	Not mentioned explicitly	Elaborate & explicit
Information reported to PHS component	Grant number; PD/PI or Contact PD/PI ; Name of Investigator with FCOI If FCOI was managed, reduced, or eliminated	INITIAL REPORT : 1995 info, plus: Name of FCOI entity; nature of FCOI, & Value by increments of \$20K; or above \$100K by increments of \$50K; how FCOI relates to PHS-funded research; basis for this determination; Key elements of mgt plan; ANNUAL: status of FCOI; changes to mgt plan

* *De minimis standard is \$0 (ANY amount must be reported) for certain types of payments.*

§ *Applies to aggregated value of interests held by investigator, spouse & dependent children.*

Topic	1995	2011
Subrecipient monitoring	...“reasonable steps” to ensure that Investigators on subs comply...	... written agreements as to whether FCOI policy of the awardee Institution or that of the subrecipient will apply; time periods to meet disclosure & FCOI report requirements. Subs relying on own policy must report FCOIs to prime to allow timely report to NIH thru the eRA-C FCOI Module.
Public Accessibility	No requirement	Identified FCOIs on publicly accessible Web site or by written response within 5 business days of request, & update as specified.
FCOI training	No requirement	Investigator must complete training prior to engaging in PHS-funded and at least every 4 years, immediately in certain circumstances.

College of Idaho's FCOI policy*

- ❖ Based on posted regulations from NIH & NSF, grant administration guides, webinars presented by NIH, draft policies of Bates College and the University of Idaho, discussions with Leslie Thompson of INBRE and grants administrators at several liberal arts colleges.
- ❖ Covers all federally funded research projects.
- ❖ Requires disclosure at submission & annual updates, or when SFIs arise, change or are discovered later.
- ❖ Requires training for NIH-funded investigators.
- ❖ In rare cases of dual funding, more stringent rules apply.
- ❖ As of 8.24.2012, no records of prior disclosure found.
- ❖ * <https://www.collegeofidaho.edu/academics/office-academic-affairs/c-i-grant-procedures/grant-resources>

FCOI Policy document



Financial Conflict of Interest Policy for Federally-funded Research

PREAMBLE: This policy is intended to comply with substantial changes in Public Health Service regulations (42 C.F.R. 50 and 45 C.F.R. 94) and to comply with conflict of interest policies of the National Science Foundation.

CONTENTS:

- A. Financial Conflicts of Interest in Research Policy
- B. Policy Applicable to Public Health Service Funding
- C. Policy Applicable to National Science Foundation Funding
- D. Other Funding Sources
- E. Enforcement
- F. Records
- G. Disclosure Statements

How do the procedures work?

- ❖ Requires disclosure of SFIs, or statement that no SFIs exist (via internal routing forms), at time of submission AND annually on anniversary date of funding (FCOI disclosure form), AND when new SFIs arise or are discovered.
- ❖ The VPAA is the responsible person for evaluating SFIs, developing management plans, training investigators, monitoring, reporting, making information available to the public, and other functions of FCOI policy. The VPAA may designate others to assist in these matters, provided that person does not possess SFIs, or that the designee is not otherwise ineligible according to federal or College policy.

Resources...

- ❖ http://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp#510
- ❖ http://www.nsf.gov/pubs/policydocs/pappguide/nsf08_1/nsf081.pdf
- ❖ http://www.nsf.gov/pubs/policydocs/pappguide/nsf11001/aag_4.jsp
- ❖ <http://grants.nih.gov/grants/policy/coi/index.htm>
- ❖ 1995 FAQs: <http://grants.nih.gov/grants/policy/coifaq.htm>
- ❖ 1995 vs 2011: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-109.html>
- ❖ Sponsored travel: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-004.html>
- ❖ 2011 NIH on line modules:
<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

Help is available

❖ Sponsored Programs

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