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New Public Health Service/NIH regulation: Investigator responsibilities

- » Under new regulations, the definition of “investigator” is broadened.
- » The disclosure threshold for financial conflicts of interest has been lowered to \$5,000.
- » Significant financial holdings are reportable if they are related to each investigator’s institutional responsibilities.
- » Sponsored travel costs related to the investigator’s institutional responsibilities are reportable.
- » The institution must train investigators on its policy and management plan to reduce or eliminate significant financial conflicts of interest.

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The public’s trust in unbiased research funded by public money has taken a nose dive. Banner headlines highlighting investigator financial conflicts of interest (FCOI) and the concomitant fear of “tainted” research results have led to the conclusion that the research may not be on the “up and up.” That could be crippling to public support for Public Health Service/National Institutes of Health (PHS/NIH) research projects.

Another factor is the increasingly complex web of research sponsors, which may be university-based but also include private sector and federal partners. The increased pressure to produce marketable therapeutics, emphasis on translational medicine (i.e., from laboratory bench to patient bedside), and decreasing budgets (especially at the state level) has made investigators’ work much trickier. Furthermore, there has been increased demand for transparency, most especially demonstrated in the public reporting of funds awarded under the federal American Recovery and Reinvestment Act of 2009 (a.k.a.,

the Stimulus Act). Transparency and public reporting will only increase.

How will the changes affect me?

That will depend on your situation. The underlying principle is that anyone, regardless of title, who may have an effect on the design, conduct, and reporting of PHS/NIH-funded research will be covered by the new regulation.¹

If you work for a domestic, foreign, public, or private institution (except a federal institution) that receives PHS/NIH funding, you are covered by the new regulation if:

- ▶ you, as an individual, receive NIH funding;
- ▶ you are designated as “key personnel” in the grant/cooperative agreement application;
- ▶ you are a consultant to or a collaborator on an NIH-funded project who has a role in the project’s design, conduct, or reporting; or
- ▶ you are part of a Small Business Innovation Research/Small Business Technology



Sullivan



Bickford

Transfer (SBIR/STTR) Phase II project (Phase I projects are exempt.)

You may or may not be covered by the new regulation if you work for a subcontractor/subrecipient on an NIH-funded project. In general, the awardee institution is charged with taking “reasonable steps” to ensure subrecipient investigators comply by such means as written agreements, subrecipient certification, reporting timeframes, and reporting FCOI. The awardee institution must review the FCOI, respond, and manage reported FCOI which meet the standard of influencing the design, conduct, and/or reporting of PHS-funded research. Key subcontractor/subrecipient personnel who are involved in the design and implementation of the project will be covered if they have significant financial interests (\$5,000 or more). In other words, the subcontractor’s investigators have to follow the same rules as the awardee institution’s investigators.

The definition of investigator (key personnel) has been broadened to include those who, due to their institutional responsibilities as defined by the institution’s financial conflict of interest policies, could affect the design, conduct, and reporting of NIH-funded research projects. Some examples of institutional responsibilities might be research, research consultation, teaching, professional practice, and service on an Institutional Review Board (IRB) committee, safety monitoring board, or institutional committee. Each institution is required to create a written financial conflict-of-interest policy, so your institution can help you to decide, if you are unsure if you’re covered by the new regulation.

What (and how much) do I have to report?

Covered persons have to disclose each financial holding which equals \$5,000 or more. You have to disclose each financial holding held

by your spouse and/or dependent children, if the discrete financial holding equals \$5,000 or more. If you, your spouse, and/or dependent children have an equity interest in and/or receive remuneration of \$5,000 or more from a publicly-traded entity within the 12 months before disclosing, that is a significant financial interest. Remuneration includes salary and payments for services which are not salary-related, such as honoraria, paid authorship, and consulting fees. Equity interest includes stock, stock options, or other ownership interest as valued through public prices or other reasonable measures to determine fair market value.

For non-publicly-traded entities, a significant financial interest is defined as any remuneration, when aggregated, which totals \$5,000 or more. The same is true for holdings of stock, stock options, or other ownership interests.

Intellectual property rights and interests, such as patents and copyrights related to the research project, must be reported as significant financial interests when income from those rights meets the \$5,000 or more threshold.

Investigators’ reimbursed or sponsored travel related to their institutional responsibilities also must be reported. Sponsored travel occurs when an investigator’s travel is paid directly to the service provider by an outside party, so the exact amount may not be easily available.

Is there anything I don’t have to report?

Yes, there are some significant financial interests which you do not have to report. Investigators do not have to report salary, royalties, or other remuneration paid by the institution if the investigator is a current employee or appointee. Investigators do not have to report remuneration from intellectual property rights assigned to the institution and agreements to share in any royalties therefrom. In situations in which the investigator

is employed by an institution *and* also has equity in a for-profit company, his/her equity would only be excluded from disclosure requirements when the for-profit company is the same institution that is applying for or receives PHS research funding for a study in which the investigator is participating. In other words, the for-profit company is the lead, not a subcontractor, in applying for and/or receiving the funds.

Income from investments such as mutual funds and retirement accounts are not reportable, as long as the investigator does not directly control the investment decision-making for the fund. If an investigator derives income from lectures, seminars, or teaching engagements, it is not reportable if the sponsoring institution is:

- ▶ a federal, state, or local government agency;
- ▶ an institution of higher education as defined in federal law (20 U.S.C. 1000 a); or
- ▶ an academic teaching hospital, academic medical center, or research institute affiliated with an institution of higher education. If the investigator derives income from serving on advisory committees/ review panels (if said committees/panels are sponsored by these same kinds of sponsoring institutions), that income is not reportable.

Who decides conflicts and what happens then?

The institution to which the grant is awarded decides whether an investigator's significant financial holdings are a conflict. That judgment is informed by whether a reasonable person could infer that such a significant financial holding could directly and significantly affect the design, conduct, or reporting of the NIH-funded grant. Furthermore, after the institution identifies the significant financial holding as a conflict, the institution must develop and implement a management plan.

That plan may include the reduction or elimination of the significant financial interest.

Help for understanding the new requirements

Before an investigator starts any PHS/NIH-funded research, he/she must be provided training on financial conflicts of interest. Each investigator must also be provided training every four years after the initial training. Immediate training must be provided when the institution's financial conflict-of-interest policy changes in a way that affects investigator disclosure requirements; an investigator is new; or an investigator is determined to be non-compliant with the institution's policy or management plan.

Summary

The PHS and NIH have issued a new financial conflict-of-interest regulation that increases investigator disclosure requirements. With some exceptions, the disclosure threshold has been lowered and all financial holdings of the investigator (including spouse and dependent children) that exceed the threshold must be disclosed. The institution now determines whether a significant financial holding is a conflict and what further action is required. The underlying principle of the regulation is the restoration of public trust that unbiased research is carried on their behalf. Over the past few years, public trust has been eroded and research arrangements (public/private partnerships) have become more complex. The regulation increases research transparency and reporting. 🗣️

Note: For the purposes of this article, NIH is used interchangeably with the Public Health Service (PHS). However, the regulation applies to the entire PHS.

1. For further information please refer to the Federal Register, Vol. 76; No. 165, August 25, 2011; Part IV; Department of Health and Human Services; 42 CFR Part 50; 45 CFR Part 94; [Docket Number NIH-2010-0001]; RIN 0925-AA53; Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors; Action: Final Rule, pages 53256-53293.