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Important Changes to Federal Oversight of Conflicts of Interest In Connection With Federally Funded Research

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I. Introduction

On Aug. 25, 2011, the U.S. Department of Health and Human Services (HHS) published in final form the long-awaited changes to the current regulations on financial conflicts of interest (FCOI) in research funded by the Public Health Service (PHS) (2011 Rule).¹ The 2011 Rule applies both to Institutions

that apply for or receive PHS support through a *grant or cooperative agreement*² and to Institutions that solicit or receive PHS research funding through a *contract*.³ It constitutes the first major revisions to PHS's conflict of interest requirements since the promulgation of its predecessor in 1995 (1995 Rule) and reflects more than two years of work since the proposed rulemaking was first announced in May 2009.⁴

For the last several years, the government, the media, the plaintiff's bar, consumer advocates, professional journals, and trade associations have been focusing intensely on financial conflicts of biomedical researchers. The mindset of these constituencies reflects a shift away from the prior public policy emphasis on encouraging financial collaboration that would accelerate the pace of innovation to a concern about the risk of bias that can jeopardize the safety of human subjects and the integrity of the research. However, they vary in their position with respect to the appropriate emphasis to place on encouraging financial collaborations that fuel biomedical discoveries.

In the 2011 Rule, HHS states that it attempts to achieve a balance between these important goals. In the preamble to the 2011 Rule, HHS identifies several factors prompting the need to revisit and update the 1995 Rule, including (a) the increasing number of "complex collaborations" involving researchers and the private

¹ "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors," 76 Fed. Reg. 53256

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(Aug. 25, 2011) (to be codified at 42 C.F.R. Part 50 & 45 C.F.R. Part 94).

² To be codified at 42 C.F.R. Part 50.

³ To be codified at 45 C.F.R. Part 94.

⁴ 74 Fed Reg. 21610 (2009).

sector; (b) the influx of capital and financial support in research from the private sector; (c) findings of deficiencies in conflict of interest compliance programs and corresponding reform recommendations by health industry and university professional associations⁵ and the Institute of Medicine⁶ (d) a 2009 report by the HHS Office of Inspector General noting “[vulnerabilities] in grantee conflict of interest detection and management programs; and (e) concerns prompted by several widely reported instances of allegedly mismanaged financial interests held by clinical researchers.⁷ At the same time, HHS notes that the stricter standards encompassed in the 2011 Rule are not intended to chill appropriate collaborations between researchers and the private sector; instead, they are “aimed at facilitating such relationships by increasing transparency and accountability so that the resulting research is considered objective and in the interest of the public.”⁸ Further, the revised purpose section in the 2011 Rule, which states that Institutions must adopt standards that “provide a reasonable expectation that the design, conduct, and reporting of research funded under [PHS] grants or cooperative agreements will be free from bias resulting from conflicts of interest”⁹ reflects a recognition that it is impossible “to ‘ensure’ the elimination of bias.”¹⁰

II. Overview of the 2011 Rule

Significant similarities exist between the 2011 Rule and the 1995 Rule, and the essential focus remains unchanged. Both Rules address only *financial* conflicts of interest of *Investigators* conducting a *particular PHS-funded research study or performing on a particular PHS contract for a research study*; neither addresses interests that are solely non-financial in nature—such as fiduciary positions or family relationships or friendships.¹¹ Also, while stricter and more prescriptive in certain respects, the 2011 Rule continues to tie a researcher’s obligations to disclose his or her interests to financial interests that exceed certain value thresholds and gives grantee Institutions substantial discretion in

⁵ See, e.g., Report of Association of American Medical Colleges (AAMC), “Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research,” (2001); AAMC Report, “Protecting Subjects, Preserving Trust, Promoting Progress II,” (2002); AAMC Report, “U.S. Medical School Policies on Individual Financial Conflicts of Interest,” Results of an AAMC Survey (2004); AAMC Report, “Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research,” (2008); AAMC Report, “In the Interest of Patients: Recommendations for Physician Financial Relationships and Clinical Decision Making” (2010).

⁶ *Conflict of Interest in Medical Research, Education and Practice*, available at http://www.nap.edu/catalog.php?record_id=12598#toc.

⁷ 76 Fed. Reg. at 53256-7.

⁸ *Id.* at 53258.

⁹ *Id.* at 53258.

¹⁰ *Id.* at 53260.

¹¹ In declining to extend the reach of the 2011 Rule, the agency noted that it “chose to retain the focus of these regulations on [financial conflicts of interest] because we believe this is a discrete area in which there is a heightened need to strengthen management and oversight. In addition, legal authority for the regulations references financial conflicts of interest specifically, e.g. 42 USC 289b-1.” *Id.* at 53258.

designing their conflict of interest programs. While Institutional Responsibilities of Investigators now come into play to a limited extent, the 2011 Rule does not address conflicts of interest that could arise from financial interests held directly by Institutions involved in the research or from financial interests held by institutional officials who are not Investigators or other members of the research team for the particular study at issue. The standard the 2011 Rule articulates for use by an Institution in assessing whether a significant financial interest gives rise to a conflict of interest is whether the interest “could directly and significantly affect the design, conduct, or reporting of PHS-funded research,”¹² and HHS explains in the preamble to the 2011 Rule that the term “significantly” is intended to mean that it “would have a material effect on the research,”¹³ rather than whether the interest creates either the *potential* of a material effect or the *appearance of such potential*.¹⁴ In these respects, the 2011 Rule implements conflict of interest reforms that may be narrower in scope than those recommended by recent industry guidance in response to the heated conflict of interest debate in the public and private sectors.¹⁵

Despite these similarities, the 2011 Rule includes several changes that will meaningfully affect the conflict of interest compliance programs of both PHS grantees and contractors. Among other things, the 2011 Rule requires Investigators and other research team members involved in the PHS-funded study at issue to report any interests that either relate to that involvement or to any of their other “Institutional Responsibilities” such as teaching, professional practice, and service on Institutional Review Boards (IRBs) or Data Safety and Monitoring Boards (DSMBs).¹⁶ It also mandates that Institutions require Investigators to update the disclosure of interests made prior to the research study both annually for all interests and promptly after discovering or acquiring a new interest, and that the Institution take steps promptly to assess whether a conflict of interest arises and if so to manage and report conflicts of interest identified during the course of the particular research study to the PHS Awarding Component.

Of particular significance are the new “sunshine” components of the 2011 Rule that require an Institution to make available to the public, either on an available website or promptly in response to requests from the public, both its conflict of interest policy¹⁷ and detailed

¹² 76 Fed. Reg. at 53283 (to be codified at 42 C.F.R. § 50.603 and 45 C.F.R. § 94.3).

¹³ 76 Fed. Reg. at 53261 (emphasis added).

¹⁴ In the commentary to the 2011 Rule, HHS notes that it applied this same approach to the definition of “manage”; that is, the definition requires that steps be taken to reduce or eliminate bias, not also to reduce or eliminate the “appearance of bias,” finding that the latter phrase was “overly broad and ambiguous.” 76 Fed. Reg. at 53262.

¹⁵ See, for example, the AAMC and IOM reports cited at Note 5. For a lengthier discussion of potentiality principle, see B. Broccolo and J. Geetter, “Today’s Conflict of Interest Compliance Challenge: How Do We Balance the Commitment to Integrity with the Demand for Innovation?” *J. of Health and Life Sciences Law*, Vol. 1, No. 4 (2008).

¹⁶ 42 C.F.R. § 50.603 (definition of Institutional Responsibilities) and 45 C.F.R. § 94.3 (definition of Institutional Responsibilities).

¹⁷ 76 Fed. Reg. at 53285 and 53290 (to be codified at 42 C.F.R. § 50.604(a) and 45 C.F.R. § 94.4(a), respectively).

information concerning financial conflicts of interest arising from significant financial interests held by senior and key personnel identified under the PHS grant application or contract proposal.¹⁸ This approach is consistent with the reliance on “transparency” as a tool to promote compliance with legal, regulatory, and ethical standards that we have seen recently in other contexts, such as federal and state sunshine laws requiring pharmaceutical and medical device manufacturers to publicly disclose their financial relationships with health care professionals.¹⁹

Also noteworthy is the provision of the 2011 Rule stating that, if an Institution adopts a conflict of interest policy that imposes stricter standards than imposed by the 2011 Rule, the Institution will be obligated to apply that policy in meeting its reporting obligations to PHS (*Stricter Standards Rule*).²⁰ If an Institution chooses to follow a more stringent policy, the 2011 FCOI Regulation requires that the Institution follow this more stringent policy and provide FCOI reports identified under this more stringent policy to the PHS entity awarding the funding within the time periods required in the 2011 FCOI Regulation. As noted in the preamble to the 2011 FCOI Regulation, HHS “weighed the possible inconsistency in reporting resulting from implementation of this provision against the possible ramifications of the PHS Awarding Component being unaware of an FCOI related to PHS-funded research that was identified by the Institution”²¹ and felt that the benefits of the Stricter Standards Rule outweighed the risks. One such risk is that this provision likely will render Institutions circumspect about adopting more stringent policies and leave them wondering whether they may and should implement different conflict of interest policies for PHS-funded and non-PHS-funded research in light of stricter standards articulated in other best practice formulations.

The Effective Date of the 2011 Rule is Sept. 26, 2011,²² and the Compliance Date for each Institution is the earlier of Aug. 24, 2012, or immediately upon publishing a conflict of interest policy that is compliant with the 2011 Rule.²³

A summary table of key similarities and differences between the 1995 Rule and the 2011 Rule is set forth in **Appendix B**.

III. Definition of Key Terms Used in the Rules

Like the 1995 Rule, the 2011 Rule uses various defined terms throughout the Rule. It modifies some of the

¹⁸ 76 Fed. Reg. at 53287 and 53292 (to be codified at 42 C.F.R. § 50.605(a)(5) and 45 C.F.R. § 94.5(a)(5), respectively).

¹⁹ See, for example, (1) Federal law: Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6002, 124 Stat. 119, 689 (2010); (2) Massachusetts: Mass. Gen. Laws ch. 111N; 105 Mass. Code Regs. 970.000; (3) Minnesota: Minn. Stat. § 151.47; and (4) Vermont: Vt. Stat. Ann. tit. 18 § 4632, amended by Act 128 (s. 88) § 33 (May 27, 2010).

²⁰ 76 Fed. Reg. at 53285 and 53290 (to be codified at 42 C.F.R. 50.604(c) and 45 C.F.R. 94.4(a), respectively). This formalizes the administrative position the National Institutes of Health has previously articulated in frequently asked questions available on its website at <http://grants.nih.gov/grants/policy/coifaq.htm> (question B.4).

²¹ 76 Fed. Reg. at 53267.

²² *Id.* at 53256.

²³ *Id.*

definitions in the 1995 Rule and introduces several new defined terms in a discreet definition section.²⁴ In any case, a solid familiarity and understanding of these terms is essential to understanding the scope and requirements of these new regulations. Therefore, **Appendix A** sets forth a glossary of key terms for reference in connection with this article.

As noted in the glossary, HHS affirmatively chose to use the term “disclosure” to refer to the sharing of information by the Investigator with the Institution, and the term “report” to refer to the provision of information on FCOIs by the Institution to the PHS Awarding Component.²⁵ While consistent with the 1995 Rule, this nomenclature differs from that used in recent health industry professional association conflict of interest guidance,²⁶ and the difference may cause at least some Institutions that already have adapted their terminology to the approach in the industry guidance to revise the policies yet again to revert to the nomenclature used in the PHS Rules.

IV. Discussion and Analysis

A. To Whom Do the Conflict of Interest Requirements of the 2011 Rule Apply?

Like its 1995 predecessor, the 2011 Rule imposes responsibilities on both Institutions (as grantees and contractors)²⁷ and Investigators. In general, the Institution is responsible for creating a conflict of interest compliance program to facilitate and monitor compliance with the standards and requirements of the Rule and for providing reports of financial conflicts of interest (*FCOI Reports*) to the PHS Awarding Component. Investigators are charged with complying with such Institutional policies, including, without limitation, the provisions

²⁴ To be codified at 42 C.F.R. § 50.603 and 45 C.F.R. § 94.3.

²⁵ 76 Fed. Reg. at 53261 (to be codified at 42 C.F.R. § 50.603 and 45 C.F.R. § 94.3, respectively). It also uses the term “disclosure” when referring to the provision of information about financial conflicts of interest to research subjects.

²⁶ See, e.g., AAMC reports cited at *supra*, Note 5. These guidance documents use the term “reporting” instead of the term “disclosure” to refer to the sharing of information by an Investigator with an Institution and the term “disclosure” to refer to the sharing of information on conflicts of interest with the human subjects in research studies. HHS noted that it declines to follow comments requesting that it align its definitions of the terms disclose and report in the 2011 Rule with how the terms report and disclose are used by the AAMC in its seminal reports on conflicts of interest. 76 Fed. Reg. at 53261. In addition, in the new Draft Food and Drug Administration Guidance governing financial interests held by Investigators on FDA-regulated studies, the FDA deploys the term “disclose” (not report) to mean disclosures by the Applicant to the FDA on FDA Form 3455. See, “Financial Disclosure by Clinical Investigators Guidance for Industry—Financial Disclosure by Clinical Investigators,” (Draft) <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126832.htm>. For additional information about this guidance, see J. Geetter and E. Isbey, “New FDA Draft Guidance Regarding Financial Disclosures by Clinical Investigators,” July 11, 2011, <http://www.mwe.com/info/news/wp0711a.pdf>.

²⁷ HHS declined to follow comments received asking that contractors be excluded on the grounds that contractors already are required to “have an effective means of complying with the terms and conditions of their contract, including regulatory obligations designed to promote objectivity in PHS-funded research.” 76 Fed. Reg. at 53259.

obligating each Investigator to disclose to the Institution his or her Significant Financial Interests (SFIs) and those of his or her spouse and dependent children.

As noted in the preamble to the 2011 Rule, the term “Investigator” has been the subject of some confusion since 1995. In an attempt to resolve the confusion, the applicable commentary and the definition in the 2011 Rule provide that the determination of who is an Investigator is driven by the individual’s role and the degree of independence with which he or she works, and *not* by his or her title.²⁸ Specifically, an Investigator is any person who is “responsible for the design, conduct or reporting of research funded or proposed for funding by PHS.”²⁹ Expressly included in the definition are the “project director” and “principal Investigator.”³⁰ Collaborators and consultants are mentioned as other possible roles that render someone an Investigator, but those terms are undefined.

On its face, the definition would appear to encompass all members of a research team for the PHS-funded study or project other than those who have no responsibility or ability to act independently. However, the 2011 Rule does afford Institutions discretion in establishing what roles should be considered “Investigator” roles, and Institutions should affirmatively and thoughtfully exercise that discretion and be as specific and explicit in their policies. For example, if an Institution believes certain roles always should be considered Investigator roles, then its policy should so state. For other roles, the policy might provide a process for making the determination and call for the development of guidelines or criteria to be used in that process. The use of a process and corresponding guidelines may be appropriate, for example, in assessing whether to include individuals bearing the title of sub-Investigator which, despite what the title suggests, in some cases may involve only tangential involvement in the study (such as identifying potentially eligible subjects but not being involved with enrollment), and the role of those who bear no title, such as study data coordinating statisticians, which in some cases may involve significant and independent work. In determining where to draw the lines, Institutions should be mindful of the Stricter Standards Rule referenced above.

In its commentary to the 2011 Rule, HHS expresses the view that the modified definition of Investigator does not meaningfully differ from the definition in the 1995 Rule or in a companion guidance that also discussed this functionality standard.³¹ Thus, Institutions should assume that PHS would apply this definition to conflict of interest policies and practices now.

B. Does the 2011 Rule Apply to All PHS-Funded Research?

The 1995 Rule did not extend to Phase I Small Business Innovation Research/Small Business Technology Transfer Research (SBIR/STTR) primarily because those applications involved “limited amounts” of funding.³² In the NPRM preceding the 2011 Rule, HHS pro-

posed such an extension due to the fact that the amount of SBIR/STTR awards have increased and now represents a considerable expenditure of public funds. In response to objections raised in comments submitted in response to the NPRM, however, HHS chose to continue to exclude such research from the scope of the 2011 Rule.³³

C. What Does and Does Not Have to be Disclosed by an Investigator under the 2011 Rule?

The 2011 Rule substantially revises the 1995 Rule’s definition of “Significant Financial Interest.” For the most part, the changes expand the scope of Financial Interests an Investigator must disclose to the Institution. Among other things, the 2011 Rule lowers the value thresholds that trigger the need to disclose, establishes different thresholds for different types of Financial Interests, and requires disclosure of a Financial Interest exceeding the thresholds to be reported if it “reasonably appears to be related to the Investigator’s Institutional Responsibilities.” The changes have significant implications for both Investigators’ disclosure obligations and Institutions’ assessment, management, and reporting obligations.

1. Investigator’s “Institutional Responsibilities”

The 1995 Rule required an Investigator to “disclose” an SFI only if the SFI reasonably appeared to be affected by the research for which PHS funding was sought and it was an interest in an entity whose financial interests would reasonably appear to be affected by the research.³⁴ The 2011 Rule widens the disclosure net to cover SFIs that relate in any way to the research study at issue and any of an Investigator’s “Institutional Responsibilities,” even if the responsibilities seem unrelated to the particular research study or government contract.³⁵ While its definition of Institutional Responsibilities provides several illustrative examples, the 2011 Rule defers to the Institution to set the scope of such responsibilities in its FCOI policy. In this regard, an Institution may wish to consider taking the two-pronged approach described above with regard to defining the term Institutional Responsibilities; that is, first, to specify in the policy certain responsibilities the Institution believes should always be considered by Investigators in determining whether to disclose a Financial Interest, and second, to include in the policy a process for making the determination on a case-by-case basis and a requirement for the development of corresponding guidelines to assist an Investigator in making that determination. The overall goal of the Institution should be the same as that underlying the 2011 Rule’s approach—to reduce to the greatest extent possible the subjectivity involved in the determination so as

²⁸ *Id.* at 53258.

²⁹ *Id.* at 53261 (to be codified at 42 C.F.R. § 50.603 and 45 C.F.R. § 94.3, respectively).

³⁰ *Id.*

³¹ *Id.*, at 53262; see also “Frequently Asked Questions” at <http://grants.nih.gov/grants/policy/coifaq.htm>.

³² *Id.* at 53260.

³³ *Id.* (to be codified at 42 C.F.R. § 50.602 and 45 C.F.R. § 94.2, respectively). The commentators raised concerns that complying with these rules could place significant burdens on grantees, who are often small with limited resources, and pointed out that the majority (56 percent) of Phase I awardees proceed to request Phase II funding, at which time they would be covered by the regulations.

³⁴ 42 C.F.R. § 50.604 (1995), replaced by 75 Fed. Reg. at 53256 (to be codified at 42 C.F.R. § 50.604).

³⁵ 76 Fed. Reg. at 53284 and 53289 (to be codified at 42 C.F.R. § 50.602 and 45 C.F.R. § 94.3, respectively).

to generate disclosures that are as complete, accurate, and consistent as possible.

2. Monetary Threshold Triggering Disclosure

The 2011 Rule further amends the definition of SFI by lowering the monetary threshold triggering an Investigator's obligation to disclose his or her Financial Interests and those his or her spouse or dependent children received. The thresholds triggering disclosure under the 1995 Rule were: (1) any equity interest that, when aggregated, either exceeded \$10,000 or 5 percent ownership in any entity; and (2) salaries, royalties, or other payments that were expected to exceed \$10,000 over the subsequent 12-month period.³⁶ The 2011 Rule establishes lower thresholds and applies different thresholds depending on the nature of the interest. First, an Investigator must disclose the following interests of himself or herself and his or her spouse and dependent children:³⁷ (a) any form of remuneration received during the 12 months preceding the disclosure³⁸ from, and any equity interest held as of the date of disclosure in, a *publicly traded entity* that, when aggregated, exceeds \$5,000; (b) any form of remuneration received during the 12 months preceding the disclosure from a *non-publicly traded entity* that exceeds \$5,000;³⁹ (c) any equity interest in a *non-publicly traded entity* regardless of value;⁴⁰ (d) income from intellectual property rights (e.g., royalties on patents and copyrights), upon receipt, from an entity other than the applicable Institution if the Investigator is employed or otherwise appointed by the Institution;⁴¹ and (e) reimbursement to the Investigator, or payment made on behalf of an Investigator, of expenses for travel related to his or her Institutional Responsibilities, unless the reimbursement or payment is by certain specified types of entities.⁴² The Institution's conflict of interest policy will specify the details to be disclosed regarding the travel expenses in order to support a determination of whether they give rise to a financial conflict of interest, which details must include at least the purpose of the trip, the identity of the trip sponsor/organizer, the destination, and the duration.⁴³

3. Exclusion of Certain Financial Interests From Disclosure Obligation

The 2011 Rule reduces interests excluded from the definition of SFIs set forth in the 1995 Rule. The uni-

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.* This is a change to the 1995 Rule's approach where aggregate remuneration from an entity would exceed the prescribed \$10,000 threshold in the 12 months following the disclosure. The 2011 Rule instead adopts a retroactive approach of measuring the aggregate remuneration over the 12 month period preceding the disclosure.

³⁹ *Id.* HHS concluded that the \$5,000 disclosure trigger achieves the proper balance between "promoting objectivity in research" and the administrative costs that would result from imposing even lower thresholds. 76 Fed. Reg. at 53263.

⁴⁰ 76 Fed. Reg. at 53284 and 53289 (to be codified at 42 C.F.R. § 50.602 and 45 C.F.R. § 94.3, respectively).

⁴¹ *Id.*

⁴² *Id.* Types of entities to which this disclosure obligation does not apply include 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.

⁴³ *Id.*

verse of excluded Financial Interests now includes the following:

a. salaries, royalties, and other remuneration an Investigator receives from the Institution s/he is employed by or otherwise appointed with;⁴⁴

b. income from seminars, lectures and teaching engagements, or from service on advisory committees or review panels if they are sponsored by or are for a federal, state, or local government agency; an institution of higher education (or research institute that is affiliated with an institution of higher education); an academic teaching hospital; or medical center;⁴⁵ and

c. an Investigator's ownership interest in a commercial or for-profit grantee Institution; and income from investment vehicles (e.g., mutual funds and retirement accounts), if the Investigator does not directly control the investment decisions made.⁴⁶

D. Responsibilities of the Institutions

The 2011 Rule increases Institutions' responsibilities for assessing, managing, and reporting FCOI, and adds a specific requirement to establish enforcement mechanisms, sanctions, and other administrative actions to ensure compliance by Investigators.

1. Public Disclosure of Conflict of Interest Policy

The 2011 Rule retains the Institution's obligation to maintain a written, enforced conflict of interest policy that complies with the PHS regulations. Consistent with the growing practice of using transparency as a compliance enforcement tool,⁴⁷ however, the 2011 Rule establishes a new "sunshine" requirement that mandates public disclosure of the policy via a publicly accessible website if the Institution maintains a presence on a publicly available website.⁴⁸ For those institutions without such a presence, the 2011 Rule mandates that these Institutions make the policy available in writing within five business days of any request.⁴⁹

2. The Conflict Process – Identification, Assessment, and Management

The 2011 Rule reorganizes and significantly expands an Institution's responsibilities for identifying, assessing, and managing potential conflicts. The Rule shifts from the Investigator to the Institution the control over determining whether a disclosed SFI is related to PHS-funded research, and if so, whether the SFI is a FCOI.⁵⁰ This approach eliminates a meaningful element of subjectivity in an Investigator's determination of what financial interests to disclose⁵¹ and is in line with recent

⁴⁴ *Id.* This qualifier was not included under the 1995 Rule.

⁴⁵ *Id.* The 1995 Rule excluded any such income if received from any public or nonprofit entities. 42 C.F.R. § 50.603 (1995).

⁴⁶ 42 C.F.R. § 50.603 (2011).

⁴⁷ See, *supra*, discussion at Note 19.

⁴⁸ 76 Fed. Reg. at 53285 and 53290 (to be codified at 42 C.F.R. § 50.604(a) (2011) and 45 C.F.R. § 94.4(a), respectively).

⁴⁹ *Id.* Note, if an Institution that does not maintain a presence on a publicly available website acquires such a presence during the time of a PHS award or contract, the Institution has 30 calendar days to post the policy on its website. *Id.*

⁵⁰ *Id.* See, 76 Fed. Reg. 53269-70 for a discussion of this shift.

⁵¹ Note, the Investigator still retains the ability to determine whether a financial interest is a significant financial interest,

industry standards and emerging best practices. The 2011 Rule directs Institutions to develop guidelines to assist the responsible institutional official, referred to as the “designated official,” in making this determination and establishes as the standard for making such determination that the designated official “reasonably determines that the [SFI] could be affected by the research; or is an interest in an entity whose financial interest could be affected by the research.”⁵² Under the 2011 Rule, a FCOI exists when the designated official “reasonably” determines that the related SFI could “directly and significantly affect the design, conduct, or reporting of the PHS-funded research.”⁵³

If an Institution determines that a FCOI exists, the 2011 Rule requires the Institution to take all necessary steps to “manage” the FCOI. The 2011 Rule uses the term “manage” to refer to any type of steps taken to address a FCOI, whether such steps involve the reduction of the risk of bias through the development and implementation of a management plan or the elimination of the FCOI.⁵⁴ The management approach must, *to the extent possible*, protect the design, conduct, and reporting of research from bias.⁵⁵ This provision responds to public comments calling for a recognition that it is impossible to protect entirely against bias and that management approaches should be diligent and good faith efforts to secure such protections. The Institution is required to monitor compliance with the management plan for the duration of the PHS-funded research project.⁵⁶

The 2011 Rule provides a non-prescriptive and non-exclusive list of possible conflict management steps, including public disclosure of the FCOI (e.g., when publishing the research), disclosure to research subjects, appointment of an independent monitor, modification of the research plan, or severance of relationships that create the FCOI.⁵⁷ These management approaches are fairly mainstream and consistent with those also recommended by recent industry guidance.

The 2011 Rule also imposes various conflict management requirements with regard to FCOIs that arise, or are discovered, after a PHS-funded research study is underway. If a FCOI was not identified or managed on a timely basis for reasons attributable to the Institution or Investigator (e.g., an Investigator’s failure to disclose

the SFI giving rise to the FCOI), the Institution is required, within 120 days, to conduct a retrospective review of the Investigator’s activities to determine whether the PHS-funded research was biased in the design, conduct, or reporting of the research.⁵⁸ Such retrospective review must document a number of prescribed elements set forth in the Rule.⁵⁹ If the Institution determines that the FCOI created any bias from the beginning of the PHS-funded study to the time of disclosure of the FCOI, the Institution must implement and submit to PHS a mitigation report containing certain findings of the retrospective review, as well as the institution’s plan of action to eliminate or mitigate the effect of the bias.⁶⁰ In addition, if a new Investigator or existing Investigator discloses a new SFI, the Institution is required to review the SFI within 60 days to determine if it is a FCOI, and, if so, develop an interim management plan to supervise and handle the identified FCOI.⁶¹ Finally, as discussed below, an Institution is responsible for making SFIs of senior/key personnel publicly available by one of two means. In the event that those SFIs need to be updated, the 2011 Rule sets the precise update procedures.

3. Public Disclosure of Certain Disclosed Interests

The “sunshine” provisions of the 2011 Rule require public disclosure of certain SFIs disclosed by a subset of Investigators that meet the definition of Senior/Key Personnel (in the case of grants) or Key Personnel (in the case of contracts). Before expending any PHS funds, an Institution now must disclose, on a publicly accessible website or via written response to any requestor within five business days of a request if the Institution does not maintain a presence on a publicly available website, information concerning an SFI that was disclosed and is still held by an individual identified as Senior/Key Personnel or Key Personnel (as applicable) on the grant application or contract (as applicable), that the Institution determines is both related to the PHS-funded research and gives rise to a FCOI.⁶² The specific information to be made publicly accessible includes the Investigator’s position with respect to the research project and the approximate value of the interest.⁶³

The information must be updated at least annually. Further, an Institution that posts information on a pub-

which involves the exercise of judgment as to whether the interest relates to his or her Institutional Responsibilities and whether it reaches the disclosure thresholds. *Compare*, the corresponding provision of the 1995 Rule at 42 C.F.R. § 50.604(c)(1) (1995).

⁵² 76 Fed. Reg. at 53285 and 53290 (to be codified at 42 C.F.R. § 50.604(f) (2011) and 45 C.F.R. § 94.4(f), respectively).

⁵³ *Id.*

⁵⁴ In contrast, the 1995 Rule was sometimes interpreted to treat reduction and elimination as distinct from management. 76 Fed. Reg. at 53262.

⁵⁵ 76 Fed. Reg. 53284 and 53289 (to be codified at 42 C.F.R. § 50.604(g) and 45 C.F.R. § 94.4(g), respectively) (emphasis added). In the preamble, HHS notes that introducing the “management plan” requirement is not only consistent with many Institutions already are doing, but also was an important means of maintaining objectivity in PHS-funded research across the research community. 76 Fed. Reg. at 53272.

⁵⁶ 76 Fed. Reg. at 53287 and 53292 (to be codified at 42 C.F.R. § 50.605(a)(4) and 45 C.F.R. § 94.5(a)(4), respectively).

⁵⁷ 76 Fed. Reg. at 53286 and 53291 (to be codified at 42 C.F.R. § 50.605(a)(1) (2011) and 45 C.F.R. § 94.5(a)(1), respectively).

⁵⁸ 76 Fed. Reg. 53286 and 53291 (to be codified at 42 C.F.R. § 50.605(a)(3)(ii)(A) (2011); 45 C.F.R. § 94.5(a)(3)(ii)(A), respectively). Further, in the event that an Institution identifies an SFI that was not previously disclosed by the Investigator or addressed adequately by the Institution for whatever reason, the designated official has 60 days to review the SFI, determine whether it is “related” and, if so, determine whether it presents a FCOI. 76 Fed. Reg. 53286 and 53291 (to be codified at 42 C.F.R. § 50.605(a)(3) and 45 C.F.R. § 94.5(a)(3), respectively).

⁵⁹ 76 Fed. Reg. 53286 and 53291 (to be codified at 42 C.F.R. § 50.605(a)(3)(ii)(B) (2011) and 45 C.F.R. § 94.5(a)(3)(ii)(B), respectively).

⁶⁰ 76 Fed. Reg. 53286 and 53291 (to be codified at 42 C.F.R. § 50.605(a)(3)(iii) and 45 C.F.R. § 94.5(a)(3)(iii), respectively).

⁶¹ 76 Fed. Reg. 53286 and 53291 (to be codified at 42 C.F.R. § 50.605(a)(2) (2011) and 45 C.F.R. § 94.5(a)(2), respectively).

⁶² 76 Fed. Reg. 53287 and 53292 (to be codified at 42 C.F.R. § 50.605(a)(5)(i) and 45 C.F.R. § 94.5(a)(5)(i), respectively).

⁶³ 76 Fed. Reg. 53287 and 53292 (to be codified at 42 C.F.R. § 50.605(a)(5)(ii) and 45 C.F.R. § 94.5(a)(5)(ii), respectively).

licly available website must update the website within 60 days of the Institution learning of any additional SFIs of Senior/Key Personnel or Key Personnel that were not previously disclosed or of SFIs of such Investigators that are new to the PHS funded research.⁶⁴ The website must indicate the date as of which the information is current and that the information is subject to being updated.⁶⁵ Similarly, in the event that an Institution does not maintain a publicly accessible website but instead responds to written inquiries, the Institution must indicate in any such written response the date as of which the information is current and that it is subject to updates, which should be requested subsequently by the requestor.⁶⁶ Institutions are required to keep all information subject to these sunshine provisions publicly accessible for at least three years from the date that the information was last updated.⁶⁷

4. Reporting to PHS Awarding Component and Internal Recordkeeping

The 2011 Rule significantly expands an Institution's obligations to report conflicts of interest related information to PHS. It incorporates the 1995 Rule's requirement that, prior to expenditure of any PHS funds, an Institution must provide PHS with a report describing any SFI that it determines constitutes a FCOI⁶⁸ and assuring PHS that a management plan has been implemented.⁶⁹ However, it requires additional, detailed information, including: (i) the project/contract number, (ii) the Project Director/Principal Investigator (PD/PI) information; (iii) the name of the Investigator with the FCOI; (iv) the name of the entity with which the Investigator has the FCOI; (v) the nature of the FCOI; (vi) the value of the SFI at issue; (vii) a description of how the SFI relates to the PHS-funded research and the basis for determining how the financial interest conflicts with the research; and (viii) a description of the key elements of the Institution's management plan.⁷⁰ The 2011 Rule also requires the Institution to provide annual follow-up reports addressing the status of a FCOI (e.g., whether FCOI no longer exists or is still being managed) and any changes to the management plan for the duration of the PHS-funded research project.⁷¹ The 2011 Rule maintains the requirement that an Institution retain all records relating to Investigator disclosures of financial interests and the Institution's response to these disclosures for at least three years from the date of submission of the final expenditures report or final payment, or any other time periods as required by applicable

⁶⁴ 76 Fed. Reg. 53287 and 53292 (to be codified at 42 C.F.R. § 50.605(a)(5)(iii) and 45 C.F.R. § 94.5(a)(5)(iii), respectively).

⁶⁵ *Id.*

⁶⁶ *Id.* It would appear, therefore, that an Institution may not have a responsibility to reissue written responses to requestors unless the Institution receives a renewed written request for updated information. However, this aspect of compliance with the 2011 Rule is not directly discussed.

⁶⁷ 76 Fed. Reg. 53287 and 53292 (to be codified at 42 C.F.R. § 50.605(a)(5)(iv) and 45 C.F.R. § 94.5(a)(5)(iv), respectively).

⁶⁸ 42 C.F.R. § 50.605(b)(1) (2011); 45 C.F.R. § 94.5(b)(1) (2011).

⁶⁹ *Id.*

⁷⁰ 76 Fed. Reg. 53287 and 53291 (to be codified at 42 C.F.R. § 50.605(b)(3) and 45 C.F.R. § 94.5(b)(3), respectively).

⁷¹ 76 Fed. Reg. 53288 and 53292 (to be codified at 42 C.F.R. § 50.605(b)(4) and 45 C.F.R. § 94.5(b)(4), respectively).

law.⁷² Importantly, this requirement mandates that the Institution maintain a copy of *all* disclosures, regardless of whether the disclosure was deemed a FCOI necessitating the Institution to implement a management plan or respond in any other manner.

5. Training

The 2011 Rule continues to require an Institution to inform each Investigator of its policy on conflicts of interest, of the Investigator's disclosure responsibilities, and of the content and scope of the 2011 Rule. However, it now also mandates that Institutions train Investigators prior to their engaging in any PHS-funded research, at least every four years, and immediately when any of the following occurs: (1) the Institution revises its financial conflict of interest policies in a manner that affects the Investigators; (2) an Investigator is new to the Institution; or (3) an Institution finds that an Investigator is not in compliance with the regulations, policies, or any management plan.⁷³

6. Subrecipients

The 2011 Rule preserves the requirement that Institutions involving subrecipients (either subcontractors or consortium members) in conducting PHS-funded research must take "reasonable steps to ensure that Investigators working for subrecipients comply with the regulations."⁷⁴ Institutions can choose one of two approaches to meeting this requirement. First, Institutions may require that the subrecipient provide written "assurances" that it will be able to comply with the 2011 Rule. Second, if a subrecipient is unable to provide such an assurance, the Institution must require that Investigators working for that subrecipient comply with the Institution's policies and procedures.⁷⁵ The agreement between the Institution and the subrecipient needs to specify which option the Institution elects. If the parties agree that the subrecipient will provide assurances, the subrecipient must report all FCOI of its Investigators to the Institution with sufficient time for the Institution to include such information in its FCOI Report to the PHS Awarding Component. If the parties agree that the Investigators affiliated with the subrecipient will comply with the Institution's policies and procedures, the subrecipient Investigators must disclose their SFIs to the Institution in sufficient time for the Institution to evaluate such SFIs in accordance with the Institution's policies and procedures.⁷⁶ HHS declined to follow suggestions made in public comments that the subrecipient submit reports directly to the PHS Awarding Component on the grounds that the Institution is the responsible party to the agency.⁷⁷ Given the significant volume of research that involves cooperative groups, consortia and other collaborations, the subrecipient provisions merit significant attention.

⁷² 76 Fed. Reg. at 53286 and 53291 (to be codified at 42 C.F.R. § 50.604(i) and 45 C.F.R. § 94.4(i), respectively).

⁷³ 76 Fed. Reg. 53285 and 53290 (to be codified at 42 C.F.R. § 50.604(b) and 45 C.F.R. § 94.4(b), respectively).

⁷⁴ *Id.* at 53285 and 53290 (to be codified at 42 C.F.R. § 50.604(c) and 45 C.F.R. § 94.4(c), respectively).

⁷⁵ *Id.* at 53285 and 53290 (to be codified at 42 C.F.R. § 50.604(c)(1) and 45 C.F.R. § 94.4(c)(1), respectively).

⁷⁶ *Id.* at 53285 and 53290 (to be codified at 42 C.F.R. § 50.604(c)(1)(iii) and 45 C.F.R. § 94.4(c)(1)(iii), respectively).

⁷⁷ 76 Fed. Reg. at 53268.

7. Sanctions

The 2011 Rule retains the requirements that an Institution establish adequate enforcement mechanisms and provide for sanctions where appropriate, and the discretionary disciplinary authority permitting PHS to direct an Institution to sanction a noncompliant Investigator.⁷⁸ However, the 2011 Rule expands the Institution's responsibility to take other administrative actions to ensure Investigator compliance as appropriate.⁷⁹ In connection with the exercise of such authority, an Institution must submit to PHS, or permit onsite review by PHS of, all records pertaining to a financial interest.⁸⁰

V. Conclusion

Balancing principled and productive collaboration between scientists and the private sector with bolstering the integrity of, and public confidence in, biomedical research is delicate and difficult. In recent years, government agencies, the media, professional associates, state governments, the federal government, and other stakeholders have demanded and attempted to articulate new standards that achieve equipoise. The 2011 Rule represents HHS's effort to articulate new requirements that respond in many respects to the concerns of these constituencies and focus on the agency's need for information to better regulate conflicts of interest in research practices and Institutional grantees' and contractors' oversight obligations and accountability for PHS-funded projects. Although it leans heavily on standards and requirements that have been in place since the rule was first published in 1995, the clarifications and stricter standards warrant careful consideration and will, in many cases, necessitate that Institutions revisit and refine their existing approaches to conflict of interest policies, procedures, guidelines, and tools.

Among other things, Institutions will need to consider how to design policies and procedures to accommodate the Stricter Standard Rule with regard to key considerations such as monetary thresholds for disclosure and whether to cover both financial interests and other interests, such as associational interests.

Of paramount importance will be whether to use the stricter "appearance" of a conflict or appearance of the potential for conflict standard recommended in certain industry guidelines. Deciding where to draw the lines will be particularly challenging for Institutions that already have revised their policies to implement those industry guidelines. Those that consider adopting different approaches for PHS-funded and non-PHS funded research will face the uncertainty inherent in the lack of guidance on that issue and the administrative challenges and potential compliance management risks of implementing and enforcing dual standards.

To the extent an Institution's conflicts policy, procedures, and guidelines do not already do so, they will

⁷⁸ 76 Fed. Reg. at 53288 and 53293 (to be codified at 42 C.F.R. § 50.606 and 45 C.F.R. § 94.6, respectively).

⁷⁹ 76 Fed. Reg. at 53286 and 53291 (to be codified at 42 C.F.R. § 50.604(j) and 45 C.F.R. § 94.4(j), respectively). The Preamble states that the 2011 Rule "makes clear that Institutions are responsible for ensuring Investigator compliance with institutional policies and procedures, and it is necessary for institutions to establish appropriate consequences for non-compliance." 76 Fed. Reg. 53277.

⁸⁰ 76 Fed. Reg. at 53288 and 53293 (to be codified at 42 C.F.R. § 50.606(b) and 45 C.F.R. § 94.6(b), respectively).

need to be revised to (1) describe the scope of the roles and responsibilities an Investigator must take into account in deciding which interests he or she must disclose and (2) provide standards and criteria for use by the designated officials in making decisions concerning whether an interest is related to and could cause bias in the research study.

Institutions also will need to enhance the administrative and technological infrastructure that supports the implementation, monitoring, and oversight of the conflicts policy to meet the website and other public reporting obligations, increased training needs and requirements, as well as the more frequent and detailed PHS reporting obligations.

Thus, although the 2011 Rule builds on the foundation provided for in the 1995 Rule, it meaningfully expands an Institution's responsibilities. Given that conflict of interest programs, policies, and procedures must be customized for the atmospheric and technical capabilities of specific institutions, Institutions should promptly begin the process of implementing compliance with the 2011 Rule.

Appendix A: Glossary⁸¹

| Term | Definition |
|---|--|
| Contractor | Means any entity that "provides property or services under contract for the direct benefit or use of the Federal Government." |
| Disclosure | Means the reporting by an Investigator of his/her Significant Financial Interests to an Institution. |
| FCOI Report | Means the report from an Institution to a PHS Awarding Component describing a FCOI. |
| Financial Conflict of Interest ("FCOI") | Means a FCOI is a SFI that "could directly and significantly affect the design, conduct, or reporting of PHS-funded research." |
| Financial Interest | Means "anything of monetary value" regardless of whether the value can be easily ascertained. |
| Institution | Means any domestic or foreign entity (including a government agency) that "submits a proposal, or that receives, PHS research funding." Institutions are also sometimes referred to as grantees or grantee Institutions. |
| Institutional Responsibilities | Means those "professional responsibilities" of an Investigator conducted "on behalf of the Institution" that are defined in the Institution's conflict of interest policies and procedures. |
| Investigator | Means the "project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research" that is covered by the 2011 Rule, and which "may include, for example, collaborators or consultants." |
| Key Personnel | Means the project director or principal Investigator and any other personnel considered to be essential to work performance in accordance with HHSAR subpart 352.242-70 and identified as key personnel in the contract proposal and contract. |
| Manage | Means "taking action to address a FCOI, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias." |

⁸¹ The defined terms are set forth on pages 76 Fed. Reg. at 53283-4 and 53288-90 (to be codified at 42 C.F.R. § 50.603 and 45 C.F.R. § 94.3, respectively).

| Term | Definition |
|------------------------|---|
| PHS Awarding Component | Means the “organizational unit of the PHS that funds research that is subject” to these regulations. |
| Research | Means any activity that is a “systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research.” The definition notes that it is intended to cover both “basic and applied research” as well as “product development” and should be understood broadly to include any “activity for which research funding is available from a PHS Awarding Component.” |
| Senior/Key Personnel | Means the project director or principal Investigator and “any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution.” |

| Term | Definition |
|---|---|
| Significant Financial Interest (SFI) | Establishes the financial interests that must be disclosed by the Investigator to the Institution. |
| Small Business Innovation Research (“SBIR”) | Means an extramural research program for small businesses and includes, for purposes of the 2011 Rule, the Small Business Technology Transfer (STTR) Program. |

Appendix B: Summary of Select Revisions to HHS Financial Conflicts of Interest Regulations

| Topic | 1995 FCOI Regulation | 2011 FCOI Regulation |
|--------------------------------------|---|--|
| Applicability | Applies to Institutions that apply for PHS funding for research and Investigators participating in research, with an exception for Small Business Innovation Research (SBIR)/Small Business Technology Transfer Research (STTR) Phase I applications. | Added language to clarify that the obligations under the 2011 FCOI Regulation continue to apply once PHS-funded research is underway (e.g., after the application process). For example, with respect to a FCOI previously reported by the Institution with regard to an ongoing PHS-funded research project, the Institution shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project. The preamble to the 2011 FCOI Regulation states that the revisions were based, at least in part, to address the fact that Institutions could be more diligent about addressing potential FCOIs at the onset of a PHS-funded research project than after the work was underway. |
| Investigator Disclosure Requirements | Requires <i>Investigators</i> to provide to their Institutions a list of SFIs that would <i>reasonably appear to be affected by the research</i> for which PHS funding is sought, and SFIs in entities whose financial interests would reasonably appear to be affected by the research. Meaning, only SFIs related to PHS-funded research <i>as determined by the Investigator</i> are required to be disclosed. | <ul style="list-style-type: none"> ■ Requires Investigator disclosures to include SFIs that reasonably appear to be related to the Investigator's "Institutional Responsibilities." |

| Appendix B: Summary of Select Revisions to HHS Financial Conflicts of Interest Regulations | | |
|---|---|--|
| Topic | 1995 FCOI Regulation | 2011 FCOI Regulation |
| | | <ul style="list-style-type: none"> ■ Two Key Inquiries: <p>(1) Who is an “Investigator” (how/who makes the determination)? The preamble to the 2011 FCOI Regulation states that the revised definition of “Investigator” emphasizes that Institutions should consider the roles of those involved in research and the degree of independence with which those individuals work, meaning that an <i>Institution</i> is expected to set the roles that trigger “Investigator” status.</p> <p>(2) What are an Investigator’s “Institutional Responsibilities” for which he/she must disclose related interests? The preamble to the 2011 FCOI Regulation states that the <i>Institution</i> must define the Investigator’s responsibilities in its policy on financial conflicts of interest.</p> <p><i>Applicable New Definitions under 2011 FCOI Regulation:</i></p> <p>“Disclosure of Significant Financial Interests”: included to clarify difference between disclosure and reporting. Describes communication from Investigator to Institution. The definition was included to create a distinction between the communications from an Investigator to an Institution and, correspondingly, from an Institution to PHS (the latter now captured in the defined term “FCOI Report”).</p> <p>“Institutional Responsibilities”: reflects new requirement that Investigator disclose SFIs related to the individual’s professional responsibilities on behalf of the Institution. Defined as “. . .including, but not limited to, activities such as research, research consultation, teaching, professional practice, Institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.”</p> <p>“Investigator”: revised to clarify that it means the PD/PI as well as any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, including persons who are subrecipients, contractors, collaborators, or consultants (or, in the case of PHS contracts, subcontractors, collaborators, or consultants).</p> |
| Significant Financial Interests (SFI) Definition | Sets a \$10,000 threshold for disclosure by the Investigator to the Institution for payments or equity interests from/in publicly-traded and non-publicly-traded entities | <ul style="list-style-type: none"> ■ Sets as the threshold for disclosure of remuneration and value of an equity interest in <i>a publicly-traded company</i>, when aggregated, at \$5,000 (lowered from \$10,000). ■ Sets as the threshold for disclosure of remuneration in <i>a non-publicly-traded company</i>, at \$5,000, but <i>any</i> equity interest in <i>non-publicly-traded</i> entities must be disclosed, regardless of value. ■ Calculates remuneration based on <i>the year prior</i> to the disclosure, rather than expected “over the next twelve months.” |

Appendix B: Summary of Select Revisions to HHS Financial Conflicts of Interest Regulations

| Topic | 1995 FCOI Regulation | 2011 FCOI Regulation |
|--|--|--|
| | | <ul style="list-style-type: none"> ■ Establishes that payment for services now includes paid authorship and reimbursed or sponsored travel related to the Investigator’s Institutional Responsibilities. Establishes that income from IP rights (e.g., royalties) is now included. |
| SFI Definition Exclusions | <p>Excludes from scope of SFI definition:</p> <ul style="list-style-type: none"> ■ “income from seminars, lectures or teaching engagements sponsored by, and service on advisory committees or review panel for, <i>public or nonprofit entities</i>”; and ■ “royalties . . . from the applicant Institution.” | <p>Retains exclusions from scope of SFI for:</p> <ul style="list-style-type: none"> ■ Income from seminars, lectures, teaching, or service on advisory committees or review panels but only if from <i>government or an Institution of higher education</i>; ■ Salary, royalties, or other remuneration paid by the Institution (if the Investigator is currently employed or otherwise appointed by the Institution); ■ Interest in mutual funds, retirement accounts, and other investment vehicles when the Investigator does not control the investment decisions; and ■ Any ownership interest in the Institution. |
| Institutional Responsibilities for Internal SFI Review | <p>Requires Investigators to determine if their SFIs are related to the research, and the Institution determines whether the disclosed SFI is a FCOI.</p> | <ul style="list-style-type: none"> ■ Transfers responsibility <i>to the Institution</i> responsible for determining whether a disclosed SFI <i>relates to the research</i> for which PHS funding is sought and <i>whether such disclosed SFI constitutes a FCOI</i>. ■ Requires Institutions to keep records on all disclosed SFIs, even those determined not to be FCOIs. <p><i>Applicable New Definition under 2011 FCOI Regulation:</i></p> <p>“Financial Conflict of Interest” or “FCOI”: a SFI that could directly and significantly affect the design, conduct, or reporting of PHS-funded research (determination made by the Institution).</p> |
| Institutional Responsibility: Reporting | <p>Requires that prior to expenditure of PHS funds, Institutions report to PHS only that a conflict of interest was identified and assure PHS that the conflict was managed, reduced, or eliminated.</p> | <ul style="list-style-type: none"> ■ Requires Institutions to provide the PHS Awarding Entity a report of any identified FCOIs. ■ Reports must include specific information including the Investigator’s name, the nature and value of the FCOI, the basis for the determination, key elements of the management plan. ■ Requires Institutional action when new SFI arises or becomes known after research has begun. ■ Specific components of the report include: <ul style="list-style-type: none"> ◆ Project/Contract number; ◆ PD/PI information; ◆ Name of the entity with which the Investigator has the FCOI; ◆ Value of the financial interest; ◆ Nature of FCOI, e.g., equity, consulting fees, travel reimbursements, honoraria; ◆ Description of how FCOI relates to PHS-funded research and basis for determining how the FCOI conflicts with the research; and |

| Appendix B: Summary of Select Revisions to HHS Financial Conflicts of Interest Regulations | | |
|---|---|---|
| Topic | 1995 FCOI Regulation | 2011 FCOI Regulation |
| | | <ul style="list-style-type: none"> ◆ Key elements of the Institution’s management plan. ■ <i>But if</i> the Institution has <i>stricter disclosure/reporting standards</i> in its own internal policies, such Institution is required to submit reports to the PHS Awarding Entity in compliance with its own policies (see discussion on “Stricter Standard” below). |
| Institutional Responsibility: Public Disclosure | Includes no public disclosure requirement. | <ul style="list-style-type: none"> ■ Requires that prior to expenditure of any funds for PHS-funded research an Institution must disclose on a publicly accessible website or in a written response to any requestor within five business days of a request if the Institution does not maintain a presence on any publicly available website: <ul style="list-style-type: none"> ◆ the SFI was disclosed and is still held by <i>senior/key personnel</i> or <i>key personnel</i>; ◆ the Institution determines that the SFI is related to the PHS-funded research; and ◆ the Institution determines that the SFI is a FCOI (including certain required information related to such FCOI such as Investigator’s name, title/role, name of the entity in which SFI is held, nature of SFI, and approximate dollar value). ■ Requires <i>the Institution to update</i> the posted information <i>at least annually</i>, and within 60 days of receipt or identification of information concerning any additional SFI that was not previously disclosed by the senior/key personnel for the PHS-funded research project, or upon the disclosure of an SFI by new senior/key personnel, if the Institution determines that the SFI is related to the PHS-funded research and is a FCOI. ■ Information <i>must remain available</i> on the Institution’s website for <i>at least three years</i> from the date that the information was most recently updated. <p><i>Applicable New Definitions under 2011 FCOI Regulation:</i></p> <p>“Key Personnel”: this designation would include the PD/PI as well as any other personnel considered to be essential to work performance in accordance with HHSAR subpart 352.242-70 and identified as key personnel in the contract proposal, <i>and</i> contract for whom FCOI information must be made publicly available. Key Personnel appear to be a subset of Investigator.</p> <p>“Senior/Key Personnel” parallel to the term “Key Personnel,” this designation would include the PD/PI as well as any other person who the Institution identifies as senior/key personnel in the grant application progress report, and any other report submitted to the PHS by the Institution, <i>and</i> for whom FCOI information must be made publicly available. Senior/Key Personnel appear to be a subset of Investigator.</p> |
| Institutional Responsibility: Management | Does not specify a specific method for addressing FCOI (manage, reduce, or eliminate are indicated as options). | <ul style="list-style-type: none"> ■ Requires Institutions to develop and implement a management for each identified FCOI (may include reduction or elimination of the SFI). |

Appendix B: Summary of Select Revisions to HHS Financial Conflicts of Interest Regulations

| Topic | 1995 FCOI Regulation | 2011 FCOI Regulation |
|---|---|---|
| | | <ul style="list-style-type: none"> ■ Requires the Institution to implement a mitigation report in the event that a FCOI was not disclosed or reviewed in a timely manner, which report shall include review and determination as to whether any PHS-funded research conducted prior to identification and management of the FCOI was biased. ■ Unlike the management plan concept in the 1995 FCOI Regulation, the 2011 FCOI Regulation introduced the concepts of “retrospective review” and “mitigation report” to address circumstances in which an Institution did not timely review a SFI, particularly when such SFI is later determined to be a FCOI. In those instances, it is now required that such SFI be reviewed and a determination made as to whether any bias was introduced into the research during the period of time prior to review and management of the FCOI. Under the 2011 FCOI Regulation, a “mitigation report” is only used in cases where the Institution determines that a <i>newly identified FCOI has resulted in bias</i> in the design, conduct, or reporting of PHS-funded research. |
| Sharing Information Publicly | Requires that Institutions maintain a written, enforced policy on conflict of interest. | <ul style="list-style-type: none"> ■ Requires that Institutions make their conflict of interest policies available on a publicly accessible website. ■ Requires that if an Institution does not maintain a presence on any publicly available website, the Institution must provide a copy of the policy within five days of any request for it. |
| Institutional Responsibility: Subrecipients | Requires that Institutions take reasonable steps to ensure that subrecipient Investigators comply with the regulations. | <p>Expands specific requirements for ensuring that subrecipients comply with the regulations including:</p> <ul style="list-style-type: none"> ■ Requiring written agreements to establish which Institution’s COI policy will apply to the subrecipient’s disclosures; and ■ In the event that the subrecipient relies upon its own policy, requiring the subrecipoint to provide FCOI reports on all subrecipient Investigators to the Institution for the Institution to report to the granting agency; or ■ In the event that the subrecipient does not rely on its own policy, requiring the subrecipient to provide subrecipient Investigator SFIs to the Institution for the Institution to access for FCOIs. |
| Institutional Responsibility: Training | Requires Institutions to inform Investigators of the conflict of interest policy and their internal reporting responsibilities. | <ul style="list-style-type: none"> ■ Requires training on the policy, the Investigator’s disclosure responsibilities, and the regulations. ■ Specifies that such training must be completed prior to the Investigator engaging in PHS-funded research. ■ Requires that training must be completed at least every two years thereafter. |

| Appendix B: Summary of Select Revisions to HHS Financial Conflicts of Interest Regulations | | |
|---|--|--|
| Topic | 1995 FCOI Regulation | 2011 FCOI Regulation |
| Institutional Responsibilities: Sanctions | <ul style="list-style-type: none"> ■ Requires that if the failure of an Investigator to comply with the conflict of interest policy of the Institution has biased the design, conduct, or reporting of the PHS-funded research, the Institution must promptly notify PHS of the corrective action taken or to be taken. ■ Requires the disclosure of any FCOI not managed if related to a PHS-funded clinical research study of the safety or effectiveness of a drug, device, or treatment in each <i>public presentation</i> of the results of the research. | <ul style="list-style-type: none"> ■ Establishes that PHS may impose special award conditions, suspend funding, or take other enforcement action, including a Stop Work Order, <i>until the matter is resolved.</i> ■ Requires requesting an addendum to previously published presentations for any FOCI not managed, if related to a PHS-funded clinical research study of the safety or effectiveness of a drug, device, or treatment. |
| Stricter Standard | Does not explicitly establish the stricter standard rule; however, guidance had stated this requirement. | <p>Requires that if Institutions have policies that are more stringent than the regulations require, FCOI reports made to PHS must be in accordance with the Institutional policy.</p> <p><i>Implications/Considerations:</i></p> <p>(1) If an Investigator has an interest that does not rise to the level of a SFI (e.g., is below the monetary threshold triggers or falls within an excepted category), but nevertheless must be disclosed (and potentially managed) under an Institution’s policy, does such an interest have to be reported to PHS, and, if such Investigator is also a “Key Personnel,” disclosed on its website?</p> <p>(2) If an Investigator has an interest that is disclosed and is not to be an FCOI because it is not related to research, but nevertheless must be managed pursuant to the Institution’s policy (e.g., an individual interest conflicts with a disclosed institutional interest, and a firewall is implemented pursuant to a management plan), would this interest be reported to PHS under this stricter standard concept?</p> <p>(3) If an Institution has policies that require that disclosures be made by persons other than Investigators (e.g., Institutional Officials), would an Institution have to report such interests if (A) they impact or relate to an ongoing research study; or (B) are assessed and managed under the Institution’s policy, but do not relate to a research study (e.g., clinical conflict)?</p> |