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Implementing the Final Rule on Financial Conflicts of Interest in Public Health Service Funded Research

Preliminary Institutional Considerations and Approaches to Selected Provisions

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I. Introduction

Background

On August 25, 2011, the Department of Health and Human Services issued the final regulations related to individual conflicts of interest in federally-funded research, entitled “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought.”¹ The publication of the final rule was the culmination of a process that began when the Department indicated its intention to modify the existing regulations through an Advanced Notice of Proposed Rulemaking in May 2009. This effort represented the first modification to the regulations since they were issued in 1995.

The 2011 regulations (subsequently referred to throughout this publication as the “new rule”) maintain the basic structure of the 1995 regulations, in which investigators provide certain information about their significant financial interests to their institutions, which, in turn, review the information, address any identified financial conflicts of interest (FCOIs) related to specific research, and provide some information to the Public Health Service (PHS) organizational unit funding the research. The new rule, however, substantially modifies the definitions, thresholds, and requirements for disclosing, reviewing, managing, and reporting financial relationships between research personnel and outside entities, requiring institutions to make significant changes to policies and processes before the implementation date of August 24, 2012.

In drafting the new rule, the National Institutes of Health (NIH) recognized that institutions vary in size, current systems, and available resources. As a result, many aspects of the new rule leave specific processes and approaches up to the institution to design, requiring only specific elements or outcomes. Many institutions that receive funding from NIH or other PHS entities expressed concerns about the implementation challenges presented by the new rule. In response to these concerns, the Association of American Medical Colleges (AAMC) held a series of invitational, one day working meetings across the country to collect practical suggestions on implementation strategies for certain provisions of the new rule.

Purpose

The goal of this report is to provide institutions subject to the new rule with some insight into how their peer institutions were thinking about these issues in the first few months after announcement of the new rule, and to provide a range of contemplated approaches. The institutions that participated in the working meetings (listed in the Appendix) represented a cross-section of AAMC member institutions in size and geographic location. Representatives came from larger and smaller, public and private institutions, from states that have their own conflict of interest reporting and disclosure laws and those that have none, from institutions with complex electronic conflict of interest disclosure and management systems and institutions with a small conflict of interest office staff and only paper files. In this report, those institutions that were represented at the meeting are referred to as “participating institutions,” but are not identified by name or representative.

¹ 76 Fed. Reg. 53256, Aug. 25, 2011. Available at http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf.

Scope and Limitations

This document represents the considerations and likely approaches of the over 50 institutions that sent a representative to one of the four regional meetings that AAMC convened in late 2011, reviewed this document and provided additional thoughts, or shared their institutions' ideas with AAMC over the past several months. It is not intended to serve as a definitive statement on how any one institution should or is planning to implement any aspect of the new rule, but is intended to demonstrate the breadth of approaches that are being considered by institutions that receive PHS funding. The report was reviewed by a number of individuals to assess the feasibility and potential compliance consequences of proposed approaches discussed here and include only those proposals that seem to meet the language and intent of the new rule, but no suggestion contained in the report should be assumed to be specifically endorsed by any reviewer or guaranteed to meet the requirements of the new rule.

This report does not address every aspect of the new rule or provide a comprehensive prescriptive approach for complying with the new rule. It does, however, represent many of the ideas and processes that arose from robust conversations about the aspects of the new rule that AAMC member institutions found most concerning or complicated. During the course of these meetings, some ideas were generated during discussion and have been further discussed since the meetings. Those ideas that gained traction in terms of feasibility among AAMC member institutions are included and highlighted here.

Organization

Each section of this report describes the approaches to a single provision (or set of related provisions) of the new rule that were proposed at one or more of the four regional working meetings and further discussed through subsequent conversations. The text provides a brief overview of the new rule's requirements, an overview of institutional concerns and the types of approaches discussed, and then a more detailed description of specific suggestions.

A Note on Terminology Used in this Publication

In this publication, AAMC uses the terms "disclosure" and "reporting" as they are used in the new rule: an investigator *discloses* certain significant financial interests to an institution, and an institution *reports* information to entities outside of the institution, such as a federal agency or the public. This is intended to ensure that this summary report echoes the requirements of the new rule, but we note that in previous AAMC publications,² the terms "reporting" and "disclosing" referred to the provision of information to an institution by an investigator and from an institution to an external entity, respectively.

² See, e.g., Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research, A Report of the AAMC-AAU Advisory Committee on Financial Conflicts of Interest in Human Subjects Research, February 2008.

II. Definition of “Institutional Responsibilities”

Regulatory Requirement

One of the most significant changes in the new rule involves the scope of interests that now qualify as “significant financial interests” that must be disclosed by the investigator to the institution through a financial interest disclosure process. Under the 1995 regulations, investigators are required to disclose certain significant financial interests to the extent the investigator deems them to be *related to research that is funded by the Public Health Service*. The new rule defines significant financial interest to include any financial interest “of the Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appears to be related to the Investigator’s institutional responsibilities”³ and that meet the regulatory thresholds. As further discussed in Section III, the determination that a disclosed interest is related to the PHS-funded research is now the responsibility of the institution, not the investigator.

Institutions are given latitude through the rule to define what activities fall under institutional responsibilities through their conflict of interest policies. The new rule defines institutional responsibilities as “an Investigator’s professional responsibilities on behalf of the Institution, and *as defined by the Institution* in its policy on financial conflicts of interest.”⁴ The new rule offers a non-exhaustive list of possible examples (research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards). How institutions choose to define this term will dictate the disclosure obligations of investigators and the scope of information for which institutions have responsibility.

Institutional Concerns and Proposed Approaches

During the AAMC working meetings, many participating institutions reported that complying with this provision of the new rule will require a revision to their definitions of significant financial interest and the inclusion of specific guidance on what is meant by “institutional responsibilities.” Some institutions indicated that their current policies and procedures are capturing this information, or something close to it; therefore, they felt that only minor tweaks will be necessary to ensure that their investigators are disclosing all financial interests related to institutional responsibilities. Others hoped that their current policy definition, although not quite specific to institutional responsibilities (for example, one institution seeks disclosures related to “professional competence”) could be reinterpreted through internal guidance and revised procedures to avoid an overhaul of the policy itself, given the administrative burden that involves.

Those institutions that were planning to revise their written policies to define or redefine “institutional responsibilities,” were considering the following approaches, which are described in greater detail below:

- Including a broad definition that does not specify categories of activities or responsibilities
- Including a prescriptive list of activities (either through defined categories or illustrative examples)

³ 42 CFR § 50.603.

⁴ 42 CFR § 50.603 (emphasis added).

Other discussions about the disclosure of significant financial interests related to institutional responsibilities included:

- Requiring investigators to disclose all financial interests, regardless of relation to institutional responsibilities
- Institutional considerations of faculty consulting agreements

Specific Discussion Topics

Broad Definition of Institutional Responsibilities

Many institutions were planning on drafting a fairly broad policy definition for institutional responsibilities. Examples discussed included “all activities that derive or descend from a faculty member’s professional standing or expertise,” “activities within an individual’s field of scientific expertise or medicine,” or some other variation that ties institutional responsibilities to the activities the investigator was hired by the institution to perform and for which the investigator is paid by the institution. Several institutions reported considering a simple cross-reference to an existing Faculty Handbook or Effort Reporting Policy as an option that would utilize a framework with which investigators are already familiar. These institutions felt that a more specific definition or concrete examples were unnecessary and might be interpreted in an overly narrow way by the investigators deciding which interests need to be disclosed.

Prescriptive List of Institutional Responsibilities

Some institutions felt that even if the definition of institutional responsibilities should not dictate which activities qualify, it would be helpful for the definition to include specific examples or categories to help guide investigators. In general, institutions contemplating the inclusion of specific examples focused on similar categories, with research, teaching, clinical, administrative, and purchasing the activities most frequently cited. Other institutions are considering a definition that references only research, teaching and “service,” under the theory that “service” should encompass all clinical care and any additional activities in the service of the institution.⁵

Broad Disclosure Requirement (Not Limited by Institutional Responsibilities)

A few institutions were considering requiring (or continuing to require) the disclosure of all financial interests, regardless of whether the interests are related to the individual’s institutional responsibilities. Some of these institutions have historically employed this very broad disclosure requirement; others are operating under state statutes that require the collection of a more comprehensive set of financial interests. In support of this approach, some institutions with a historically broad disclosure requirement noted that some investigators still fail to disclose completely. They questioned whether permitting investigators to make judgment calls about which financial interests relate to their institutional responsibilities, no matter how carefully the term is defined, would lead to under-reporting. They also noted that investigators’ financial interests, whether or not directly related to the institution or specific

⁵ At least one institution registered a concern that collecting prescriptive information related to institutional responsibilities may box institutions in with respect to effort reporting obligations. Most institutions felt that this should not be an issue, assuming the definition of institutional responsibilities applied broadly to all faculty members as the types of responsibilities one *might* have on behalf of an institution, as opposed to dictating individual responsibilities for each investigator.

research, may be publicly questioned or criticized, which counsels in favor of the institution knowing as much as it can about the financial interests and activities of its faculty and staff. On the other hand, it was recognized that a potential downside of casting such a wide net is that the institution must then determine what to do with the information it receives. Some participating institutions expressed concern that the new rule may require institutions to evaluate all the information received, because the new rule requires the institution to follow its own policy if it is more stringent than the new rule requires.⁶ Other institutions acknowledged that concern but noted that collected information that is unrelated to an individual's institutional responsibilities would likely be unrelated to the research in question and therefore would not meet the definition of an FCOI for purposes of the new rule.

Inclusion of Consulting Agreements

Many participating institutions agreed that consulting for external entities is not itself an "institutional responsibility" because the institution does not pay its faculty and staff to consult on behalf of third party entities or require them to do so. One institution described consulting as a "privilege" for faculty, not an obligation. However, it was also generally recognized that to the extent an individual is asked to consult *because of* their field of scientific expertise, clinical work, or research, certain consulting arrangements may reasonably appear to be related to an investigator's institutional responsibilities. In addition, several institutions noted that consulting agreements may raise conflict of commitment concerns, and may already need to be disclosed to department chairs for review or approval under current institutional policy.

Most participating institutions planning to limit disclosure of significant financial interests to those related to institutional responsibilities did not think that consulting income would have to be disclosed to the institution *unless* the subject matter of the consulting reasonably appeared to be related to the individual's institutional responsibilities and the amount of compensation met the institutional threshold for disclosure. For example, consulting on issues related to clinical care was generally viewed as triggering a disclosure obligation. Certain areas (such as a physician consulting on an engineering matter outside of his or her clinical expertise) were still under discussion at many institutions.

We note that participating institutions discussed their varied practices with respect to review and oversight of investigators' consulting agreements. Some institutions require institutional review of proposed consulting arrangements and all contract language, others delegate such matters to the oversight of the relevant department chair, and some do not review in any way these external consulting arrangements, leaving it to their faculty and staff to make independent judgments about whether to participate in a given consulting activity or to agree to the terms of a proposed consulting agreement.

⁶ "If an Institution maintains a policy on financial conflicts of interest that includes standards that are more stringent than this subpart (e.g., that require a more extensive disclosure of financial interests), the Institution shall adhere to its policy and shall provide FCOI reports regarding identified financial conflicts of interest to the PHS Awarding Component in accordance with the Institution's own standards and within the timeframe prescribed by this subpart." 42 CFR 42 CFR § 50.604(a).

III. Institutional Determination of Relatedness

Regulatory Requirement

A key difference between the 1995 regulations and the new rule is the shift of responsibility from investigators to institutions in determining which identified significant financial interests *relate* to an investigator's PHS-funded research. As in the 1995 regulations, an FCOI analysis is only required for those significant financial interests determined to relate to PHS-funded research. However, for institutions the new rule both increases the volume of disclosures (by requiring disclosure related to "institutional responsibilities," as discussed in Section II) and requires that the institution make the determination of whether those disclosures relate to the PHS-funded research prior to the FCOI analysis. This "relatedness" determination is now the first step for institutions in determining whether an FCOI exists. Under the new rule a significant financial interest is *related* to the PHS-funded research if an institution, through its designated official(s), "reasonably determines... [that the significant financial interest] could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research."⁷

Although institutions have ultimate responsibility for determining relatedness, the new rule recognizes a role for investigators to play in providing information relevant to the relatedness determination, and specifically provides that "the Institution may involve the Investigator in the designated official(s)'s determination of whether a significant financial interest is related to the PHS-funded research."⁸

Institutional Concerns and Proposed Approaches

This aspect of the new rule is causing some consternation among institutions that have, consistent with the previous federal requirements, historically relied on investigators to report only those significant financial interests that relate to their research. Institutions have not had to question the accuracy of investigators' judgments with respect to relatedness, and were required to evaluate as potential financial conflicts of interests only those significant financial interests that were disclosed by the investigator, and thus presumed to be related to the PHS-funded research.

In discussing the relatedness analysis, institutions expressed two primary concerns: (1) from a pure volume standpoint, this shift of responsibility may increase dramatically the resources necessary for compliance;⁹ and (2) institutions may not have the necessary expertise to identify, from a list of all significant financial interests related to an investigator's institutional responsibilities, which are or might be related to the PHS-funded research. Suggested institutional approaches sought to balance these two concerns and consider the most efficient and effective use of available or new resources.

Participating institutions had varied approaches in mind for how best to include the investigator in the process and how much of a new process would be required, given the institution's increased

⁷ 42 CFR § 50.604(f).

⁸ 42 CFR § 50.604(f).

⁹ Many institutions noted that the volume of disclosed significant financial interests may increase exponentially when taking into account both the broader disclosures (to those related to institutional responsibilities, not just the specific research) and the new rule's lowered dollar threshold for significant financial interests from \$10,000 to \$5,000 for remuneration or equity interest in publicly traded entities. One institution predicted a 3-fold increase in the number disclosures as a result of the lowered dollar threshold alone.

responsibilities under the new regulations. The primary themes and considerations discussed by the participating institutions, with special attention to the roles of the investigator, department chair, institutional official, and conflict of interest committee or office, are described below and include the following:

- Assigning responsibility within the institution for assessing relatedness, including engaging department chairs, tiered approaches to internal review, and coordination across the institution
- The timing of making the relatedness determinations
- Whether institutions should assume relatedness and concentrate on the potential impact of the significant financial interest
- How to involve investigators in determining relatedness and what additional diligence to conduct
- Documenting relatedness determinations

Specific Discussion Topics

Assigning Responsibility for Assessing Relatedness

Participating institutions described some varied approaches to who would carry responsibility for the relatedness determination at the institution. Some institutions envisioned shifting to, and resourcing, a centralized process with an institutional office charged with this task (to the extent such an office does not currently exist). Others felt strongly that department chairs have an important role to play in making at least the relatedness determination and that such analyses could occur at a more localized departmental level. This assessment would then feed information about relatedness into the conflict of interest (COI) committee process for determining if significant financial interests are FCOIs. It was reasoned that including department chairs in a shared-responsibility model creates a culture of compliance around conflicts at multiple levels of an organization, rather than having all aspects of the conflict evaluation occur behind closed doors at a COI committee meeting. Furthermore, department chairs may be closer to facts relevant to a relatedness determination, and have the additional incentive to review significant financial interests in order to identify any conflicts of commitment.

Some institutions noted that engaging department chairs in this assessment could create tension between chairs and faculty members if the chairs do not currently evaluate the outside activities of department members. Additionally, some institutions noted that department chairs may not have the necessary objectivity, available time, or substantive investment to ensure consistent evaluation from every department.

A middle ground approach under discussion at some institutions would involve a tiered structure of review based on risk. For routine review of significant financial interests or those below a certain threshold, the department chair or other similar individual would make the relatedness determination in order to identify those significant financial interests for which an FCOI analysis is warranted. When disclosed significant financial interests are over a certain threshold amount (institutions suggested amounts between \$25,000 and \$50,000) or there are other factors that raise the risk level, such as when the PHS-funded research at issue is a clinical interventional protocol, both the relatedness determination and FCOI analysis may be conducted or reviewed by an institutional decision-maker or COI office beyond the investigator's department chair.

Regardless of the specific process contemplated, there was recognition by participating institutions that a potential positive impact of this new requirement may be an incentive to synthesize what has historically

been a piecemeal system of disclosures; if institutional officials have responsibility for the relatedness determination, it may be even more critical that the official knows about all existing financial disclosures that may be coming to the institution through various gatekeepers (the IRB, technology transfer offices, annual general conflicts disclosure, etc.). Institutions had a sense that under the new rule they will now be more directly responsible for the “right hand knowing what the left hand is doing,” and that this could be a motivator to effectively coordinate different processes.

Timing the Relatedness Determination

Regarding the timing of the relatedness determination, although some participating institutions favored performing the analysis at the time an investigator is submitting a grant proposal or, for human subjects work at the time of IRB review, others felt that given the currently low funding odds and amount of change that can occur to a project prior to a funding award being granted, the analysis should be delayed until the time of the notice of grant award or Just-in-Time notification.

Assuming Relatedness

As discussed in Section II, it should be noted that some institutions are already making the relatedness determination, having historically required that investigators disclose all financial interests regardless of the relationship to their work. Of those, at least one has taken the position that the relatedness determination should not be the focus of the institution’s assessment and instead assumes that all disclosed financial interests are related to the investigator’s work. This institution elects to focus only on determining whether any of the disclosed financial interests meet the definition of an FCOI (that the financial interest “could directly and significantly affect the design, conduct, or reporting of the PHS-funded research”¹⁰). Although this approach deprives the institution of the ability to screen out any significant financial interests from needing the FCOI analysis, this institution assumed as a general rule that most disclosed interests are related, so moving directly to the FCOI analysis saves time. The viability of this approach may be dependent on an institution’s chosen process; if all FCOI determinations are required to be made by a single COI committee, the resulting volume may make such a process infeasible.

Eliciting Investigator Input and Conducting Additional Diligence

Most participating institutions agreed that investigators would continue to be an important resource for institutions in the relatedness assessment, although the anticipated approach to eliciting their input varied significantly. Some institutions discussed asking for an investigator’s assessment of relatedness for each disclosed significant financial interest and then evaluating and confirming that assessment at the institutional level in a more formal way. Others spoke of performing an institutional analysis first and then asking the investigators to confirm it or, conversely, asking investigators to defend why a certain significant financial interest is *not* related if that appears to be a possibility. Still others expressed a preference for asking pointed questions of investigators, the answers to which would aid the institution in its relatedness determination, as opposed to asking investigators to opine on relatedness directly. Many institutions echoed a general sentiment that investigators do not always make relatedness determinations accurately, not because of an intent to deceive, but due to misunderstanding the standards or not thinking broadly enough about *perceived* conflicts.

¹⁰ 42 CFR § 50.604(f).

Participating institutions fell along a continuum with respect to how much weight they thought would be given to an investigator's assessment of relatedness as opposed to conducting independent diligence designed to answer the relatedness question.

Some institutions are considering relying heavily on the investigator's input, with minimal added diligence. Institutions taking this approach might rely on an investigator's representations as to certain facts relevant to the relatedness assessment without conducting an independent analysis to confirm. The rationale cited for this position is that the investigator is often in the best position and has the requisite expertise to know whether any nexus between a financial interest and his or her research exists. Furthermore, this is a role that investigators are accustomed to playing under existing rules, and asking investigators to comment on potential relatedness may trigger the investigator to think more carefully about whether his or her disclosures are sufficient.

Understanding that the institution has the ultimate responsibility for making the relatedness determination, some institutions planned to take the approach described above coupled with monthly spot audits to determine whether investigators' representations matched an independent assessment. Other institutions planned to reserve the right to make individualized judgment calls about the required level of additional diligence based on a specific investigator's level of research activity, number of disclosed related interests (very high or very low), or prior identified FCOIs. When such individuals submit projects, rather than relying on the investigator representations in the applications to the IRB and/or COI committee or office, a more comprehensive review might be conducted.

It was pointed out on more than one occasion by a participating institution that conducting an independent relatedness analysis requires scientific expertise in order to understand the aims of a specific project clearly enough to determine whether identified significant financial interests might be affected by or be in companies whose financial interests are affected by the PHS-funded research. Institutions agreeing with this premise fell mostly at the "high diligence" end of the spectrum and identified specific affirmative steps to determine whether a connection exists between a certain financial interest and the investigator's PHS-funded research. Some specific steps discussed include:

- ensuring that the committee or body making the relatedness determination includes a scientist from a related field;
- having an independent scientist read the specific aims of a research protocol or grant and determine whether a company's product is a tool used to study an aim (and thus incidental to the aim) or is the actual subject of the research;¹¹
- comparing the financial disclosures and representations made by each person listed on a specific grant for consistency;
- checking whether any company sponsor or manufacturer listed in the grant or protocol is a wholly owned subsidiary or direct competitor of a company listed in an investigator's disclosure;
- if only drug compounds are listed (without an associated manufacturer), determining whether those compounds reflect a drug that is marketed or licensed by a company that is represented on an investigator's disclosure;

¹¹ This distinction would be relevant for those institutions that do not consider products used only as tools to raise conflict issues, a matter of debate among the participating institutions.

- coordinating with the technology transfer office to determine whether the research, as described in the protocol or grant, would impact any existing intellectual property rights or create any new intellectual property rights that might be impacted by the research; and
- seeking clarifying information from the investigators as necessary throughout the process.

Documenting the Relatedness Determination

In addition to having a process for making the relatedness determination, some participating institutions noted that they would also be internally documenting the rationale for their conclusions. It was recognized by some that in a report to PHS about an FCOI determination, the relatedness assessment may be sufficiently integral to that analysis as to be included in the report. However, for significant financial interests that are determined to be related but are ultimately determined *not* to constitute FCOIs, many institutions indicated that they would simply be documenting the internal relatedness decision-making process, either through the minutes of the COI committee (assuming the relatedness assessment comes before the committee to decide) or as separate notes of the process. Some institutions suggested that regularly providing substantial details underlying the relatedness judgment would be burdensome, and a more consistent approach of simply noting that a significant financial interest “was determined not to be related pursuant to institutional procedures” would better protect resources and privacy for investigators. Other participating institutions felt that having more specificity in committee minutes and other documents would better protect the institution by clearly documenting that a reasoned judgment was made, particularly if it was concluded that a certain significant financial interest was not related to the PHS-funded research.

IV. Development of Management Plans and Financial Conflict of Interest Reports

Regulatory Requirement

If a significant financial interest is found by the institution to “relate” to PHS-funded research, the institution must then determine whether the significant financial interest constitutes an FCOI. An FCOI exists when the institution, through its designated official(s), reasonably determines that the significant financial interest “could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.”¹² If an institution determines that a significant financial interest that is related to an investigator’s PHS-funded research rises to the level of an FCOI, then it has an obligation to develop and implement a management plan,¹³ monitor investigator compliance with the management plan on an ongoing basis until the completion of the research,¹⁴ and make an FCOI report to the PHS Awarding Component.¹⁵ The standard in the new rule for what rises to the level of an FCOI is unchanged from the 1995 regulations; however, given the consequences of finding an FCOI (for example, the reporting of management plans discussed in this section and the retrospective reviews and mitigation reports discussed in Section V) the significance of such a finding has increased.

Institutional Concerns and Proposed Approaches

Participating institutions discussed at length the processes for determining that an FCOI exists and implementation of the subsequent requirements triggered by that determination: developing management plans, monitoring investigator compliance with those plans, and generating the FCOI report. It was expressed by one participating institution that under the new rule “adverbs matter” and some institutions will be taking a harder look at what it means to affect research “directly and significantly.” The proposed approaches and concerns included:

- The relationship between the threshold for disclosure and the FCOI determination and related analysis
- Determining what should be included in a management plan, including a discussion of management elements
- Generating and documenting management plans
- Monitoring the implementation and adherence to the management plan
- Creating FCOI reports to the PHS funding unit regarding key elements of management plans

¹² 42 CFR § 50.604(f).

¹³ 42 CFR § 50.605(a)(1).

¹⁴ 42 CFR § 50.605(a)(4).

¹⁵ 42 CFR § 50.605(b).

Specific Discussion Topics

Threshold for Finding an FCOI

It was recognized during the discussions related to management plans that the new rule does not impose a de minimis threshold for finding an FCOI and institutions have discretion and flexibility in establishing the standards for determining which significant financial interests “directly and significantly” affect PHS-funded research. Many institutions took the position that absent very unusual circumstances they would never identify financial interests below \$5,000 as an FCOI, even if the institution imposed a lower disclosure threshold. Some institutions felt that as a general rule the threshold for finding an FCOI and triggering a management and reporting obligation would be much higher, noting that the \$5,000 regulatory de minimis applies only to the definition of a significant financial interest, not to the FCOI determination. All participating institutions recognized that most determinations would need to be made through a case-by-case analysis, with the value of the financial interest just one piece of the algorithm.

Content of Management Plans

The development of management plans is not a new task for institutions and has existed in some form since the 1995 regulations; however, given the new regulatory specificity regarding the content of such plans, the new reporting requirements and the corresponding increase in scrutiny on these plans, many institutions appear to be pausing to consider their current approach to managing identified FCOIs. The new rule provides a non-exhaustive list of seven conditions or restrictions that might be imposed on an investigator through a management plan.¹⁶ Participating institutions reported currently using many different techniques to manage identified FCOIs, and noted that the elements identified by NIH included the most common approaches to managing conflicts, including disclosure of the FCOI to the public or research subjects, independent monitors of the research, or modifications to the research plan, personnel, or the financial interest. Despite the new rule’s specificity in terms of providing examples of possible management plan elements, institutions appeared to retain some skepticism and confusion over what elements would ultimately be deemed adequate, and were hopeful that additional guidance or discussions with NIH program staff would confirm that the approach they are currently taking with respect to managing FCOIs would be sufficient under the new rule.

Participating institutions debated whether certain approaches qualify as “management” techniques, or whether they are more appropriately characterized as routine practices or as necessary consequences of an identified FCOI. An institution’s conclusions in these matters will impact whether these approaches are included in any proposed management plan or not. For example, institutions had different thoughts on whether disclosing FCOIs to subjects during the informed consent process constituted “managing” the conflict or merely providing information relevant to subjects’ decisions whether to participate in a given research study, as required by applicable federal regulations. This concern was raised notwithstanding the fact that the new regulations cite this as one possible example of a condition or restriction that might be used to manage an FCOI. The same question was also raised with respect to the use of independent data monitors and whether those could be employed as management tools or were simply required depending on the nature of a given study.

¹⁶ 42 CFR § 50.605(a)(1).

Several participating institutions cited their use of “data stewards” or other data oversight committees, which may go beyond the traditional role performed by a Data Safety Monitoring Board (DSMB) and are intended to ensure independence in data analysis. While certain participating institutions reported having successfully used this as a management tool and expected to continue its use, others expressed concern that such an approach would not be embraced, given their institutional culture.

Some institutions noted their practice of instituting firewalls in laboratories when there is a sponsored agreement for research, so that there is at least a part of the laboratory that has no relationship to the sponsored project and cannot be involved with the project. However, other institutions expressed concern that this approach could be seen to undermine academic freedom.

Some institutions noted the possibility of including in a management plan the instruction that investigators comply with specific existing requirements such as the institution’s faculty handbook, but others questioned whether asking investigators to do what they are already required to do can appropriately be characterized as additional “management” of an identified conflict. Several institutions felt that if an instruction to comply with an internal policy was coupled with the additional requirement that the investigator report back on his or her compliance or be monitored in his or her compliance it might rise to the level of management and was appropriate to include in a management plan.

Generating and Documenting Management Plans

Regarding the process for generating a management plan, many institutions stated that they currently used or were contemplating introducing a fairly standardized process where the possible elements of a management plan are available in standardized template format and then tailored to a given situation. Some institutions had this process in electronic form, such that a menu of options was available to the COI committee or other individual preparing the plan, and could be selected and tailored as necessary to the given circumstances under management. This system would then generate a report that could be both provided to the investigators and reported to the funding entity, as well as shared with other relevant institutional offices such as the IRB, technology transfer office, compliance office, or biosafety committee. Some institutions discussed the possibility of moving towards a system where management plans are “relationship based” as opposed to study or project specific; these types of plans would then have an addendum on which specific covered studies could be included. This may be appropriate for investigators with longstanding ongoing relationships with certain companies.

It was recognized that only some of the elements of a given management plan will be relevant to the federal funding entity and that other requirements not related to an FCOI might be imposed on an investigator but would not be reported. As such, many institutions agreed on the benefit of creating a system that can separate management plans into two sections; one that would include all of the elements relevant to the PHS funding entity, and the other for any additional requirements or conditions the COI committee or other oversight process felt it was appropriate to include. Ideally, the system could be structured so that the key elements could be automatically generated for federal reporting purposes, while the plan in its entirety could be provided to the investigator. (See below for additional discussion regarding the content of the COI report provided to the federal funder.)

Many of the participating institutions are currently requiring investigators to either acknowledge or formally rebut the generated management plan, and plan to continue this practice. Some institutions also have a process requiring students or trainees to sign a document acknowledging any FCOIs identified for a mentor.

The new rule requires a management plan to be developed and implemented prior to spending any of the related grant money. Several institutions noted that currently they hold funding until the investigator agrees to the management plan. Others use additional processes to ensure investigator acknowledgement of the management plan, from delaying submission of protocols to any required review committees until such acknowledgement or rebuttal is provided, to an escalating notification system that could include reporting to a Provost-level official or the threat of non-renewal of faculty appointment.

Monitoring Implementation of the Management Plan

It was noted by several institutions that the new requirement for monitoring management plans puts them in the position of policing investigators instead of trusting in the professionalism of their faculty and staff. Currently, many of the participating institutions are not routinely checking to determine if a management plan is being followed unless there has been some compliance issue identified, or if the management plan requires that a report of some sort be submitted to the IRB, technology transfer office, or other department, a requirement that can easily be verified. Many institutions currently include a clause in the management plan indicating that the plan is subject to audit, allowing for that possibility.

There were a variety of possible management plan monitoring models offered for consideration.

- On one end of the spectrum were institutions that were considering a self-certification approach whereby the investigator attests to the institution that compliance with the management plan has occurred. This might be followed with annual or periodic requests for confirmation that the plan is still being followed.
- Another approach involved relying on the Dean or department chair to monitor at the departmental level, again with the added incentive of identifying any conflicts of commitment.
- Other institutions were considering taking more affirmative steps to confirm implementation of a plan, such as reviewing publications and presentations for required disclosures, and asking to see press releases prior to issuance.
- At least one institution currently employs in-person meetings with every investigator under management, at which they review in detail the steps the investigator has taken, look at publications and presentations, and discuss the investigators' actions to implement the plan (but do not do any other independent diligence).
- Several institutions anticipated taking a sampling approach to monitoring, based on a sampling algorithm or other risk-based model, in order to spot-check investigator compliance. There was some support for incorporating oversight of a management plan into the plan itself as one of the conditions, for example requiring monitoring by an assigned ombudsman; again, volume and resources would be a consideration in terms of the feasibility of this type of approach.

One representative described the following fairly comprehensive monitoring process currently in place at a participating institution:

A draft management plan is submitted to the investigator and the department chair for review. If either the investigator or the chair have concerns regarding any aspect of the draft plan, they notify the institution's Conflict of Interest Program of the concerns. Once the concerns have been resolved and the draft plan modified as needed, the investigator confirms acceptance of the plan. The final management plan reflects that the investigator agreed in an email on a specific date to comply with all elements of the plan. A follow-up email is generated and sent to the

investigator 90 days later asking for confirmation that the investigator is fully in compliance with the plan and, if not, to advise the Program when they have achieved full compliance. Annual follow-up emails are then sent asking the investigator to confirm compliance so long as the plan is in effect. To the extent the plan requires the investigator to make disclosures in publications, to students, colleagues, patients, or research subjects, the Program may request copies of those disclosures. In addition, each COI committee meeting includes discussion of who has confirmed compliance with their plan.

In discussing how their conflict of interest policies would capture the new rule's monitoring requirement, many institutions voiced a preference for keeping the policy broad and simply stating that monitoring would occur, as opposed to specifying the process, to allow for flexibility and risk-based stratified approaches as needed.

Content of FCOI Reports

Many participating institutions expressed consternation about identifying the appropriate "key elements" of the management plans to NIH or other PHS funder to meet the requirements for the FCOI report discussed in the new rule.¹⁷ Conversations between AAMC and representatives at NIH have clarified that NIH program directors will be looking to receive only the key elements of the management plan, not copies of every document or correspondence provided to the investigator. As noted by an NIH representative and several institutions, the information provided to NIH may be the subject of a Freedom of Information Act request, and as such its confidentiality cannot be ensured. Furthermore, NIH does not want to receive and process more information than what the regulations require.

The important point was made during the discussions that management *activities* in general do not trigger a reporting obligation to NIH or other entity; the determination that an FCOI exists is what triggers that requirement. As many institutions noted, they may choose to manage (or "address") many types of circumstances or concerning behaviors that would not constitute an FCOI, and continuing to do so will not create a reporting obligation.

These considerations underscore the importance of a system through which a report *specific to the requirements of the new rule* can be generated, separate from the detailed plan provided to an investigator, department chair, or COI committee. As discussed above, many institutions are contemplating separating out in a section of the detailed management plan (in bulleted format) those elements that would be of interest to the PHS funding entity such that they can be collected into a report, while maintaining separately any other management issues or discussion that would not pertain to the PHS-required elements. As an additional process point for consideration, several institutions noted the importance of being transparent with the investigator regarding the elements and information that are ultimately sent to the funding agency. Although the investigator will necessarily have been intimately involved in the content of the entire management plan, it is important for the investigator to know what information was communicated to the PHS funder in the event the investigator receives a direct follow-up communication or request for clarity from the program officer.

¹⁷ "Elements of the FCOI report shall include... A description of the key elements of the Institution's management plan, including: (A) Role and principal duties of the conflicted Investigator in the research project; (B) Conditions of the management plan; (C) How the management plan is designed to safeguard objectivity in the research project; (D) Confirmation of the Investigator's agreement to the management plan; (E) How the management plan will be monitored to ensure Investigator compliance; and (F) Other information as needed." 42 CFR 50.605(b)(3)(viii).

V. New Information, Retrospective Reviews, and Mitigation Reports

Regulatory Requirement

The new rule introduces specific institutional responsibilities regarding information that may arise in the course of an ongoing PHS-funded research project. Specifically, if an investigator joins an ongoing project and discloses a significant financial interest, or an existing investigator discloses a new significant financial interest during the course of the project, the institution has sixty days to review the disclosed significant financial interest, make both the relatedness and FCOI determinations, and implement a management plan as appropriate.¹⁸

This process is essentially the same as is required for significant financial interests disclosed at the start of a project, but the obligations apply to new information on a rolling basis. To the extent information is learned that is not “new” but was not reviewed and assessed by the institution prior to the commencement of a project as required (e.g. a significant financial interest is identified that was not timely disclosed by the investigator, timely reported by a subrecipient, or timely reviewed by the institution for whatever reason), the institution has sixty days to conduct the relatedness and FCOI determinations. If an FCOI is identified, the institution must implement a management plan. In addition, if the FCOI was not identified or managed in a timely manner due to noncompliance by the investigator or the institution (including because of a failure by the investigator to timely disclose, a failure by the institution to review or manage, or a failure by the investigator to comply with an imposed management plan), the institution has 120 days from the date the non-compliance was identified to complete a retrospective review of the investigator’s activities and the research project itself to determine whether there was any bias in the design, conduct or reporting of the research as a result of the FCOI.

Institutions are required to document the retrospective review, including certain elements specified in the regulations (project number; project title; project director or principal investigator (PD/PI); name of the investigator with the FCOI; name of the entity with which the investigator has an FCOI; reason(s) for the retrospective review; detailed methodology used for the retrospective review; findings of the review; and conclusions of the review). If an FCOI is identified, the institution is required to update the FCOI report to include the actions that will be taken to manage the FCOI going forward. Furthermore, if the retrospective review finds bias in the research, the institution is required to develop and submit a mitigation report to the PHS funding agency. The mitigation report must include, at a minimum, the key elements documented in the retrospective review, a description of any impact of the bias on the research, and the institution’s plan to mitigate the effect of the bias. Institutions are then required to submit annual FCOI reports addressing the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research.

Institutional Concerns and Proposed Approaches

Early after the new rule was issued, implementing this particular area of the new rule was a task with which participating institutions appeared to struggle, and many representatives expressed feeling overwhelmed at the prospect of creating a system to collect and review new information or identify

¹⁸ 42 CFR § 50.605(2), (3).

significant financial interests that were not properly reported, conducting retrospective reviews for bias, and developing mitigation plans in a timely matter. As a threshold matter, one important point of clarification is that the requirements to conduct a retrospective review and develop a mitigation plan are not required merely because new information comes to light. This is true even when the newly learned information should have been known to the institution but was not, due to the fault of the investigator or the institution itself. The new information must first be found to be an FCOI before the requirements are triggered. This may incentivize institutions to apply stringently the standards for determining whether an FCOI exists.

There was a general consensus among the participating institutions that institutional policies on this point should be fairly broad and permit any appropriate process to flow from the identification of new information. Examples of proposed language or approaches included: “if there is new information the institution will conduct an appropriate review to determine if the significant financial interest is related to the research and if the significant financial interest is an FCOI” or telling investigators that if they fail to disclose significant financial interests in a timely manner, the institution will be required to evaluate them and conduct retrospective reviews if it is determined that any of them constitute FCOIs.

Participating institutions shared their thoughts and possible approaches regarding the following issues:

- Establishing a mechanism for uncovering and collecting new information
- Developing processes for conducting a review of newly identified FCOIs for bias, including many discussions regarding the appropriateness and applicability of currently existing review procedures
- Creating mitigation reports, including when and how mitigation plans could differ from the management plan that would have been implemented

Specific Discussion Topics

Process for Collecting New Information

Institutions expressed some concern regarding how best to ensure that new information is caught. Some institutions indicated that they would train investigators and include in relevant policies an obligation to report any new information to the institution within a very short timeframe to allow the institution to conduct a timely review. Although human subjects research projects have at least the opportunity for utilizing the IRB to review any new investigators and financial disclosures through the continuing review process, the same is not always the case for basic science. There was consensus among participating institutions that institutions do not have an obligation to go hunting for missed or new information, but those institutions currently doing systematic reviews of public websites and other types of monitoring activities are considering the steps that may flow from information learned through those processes.

Determination of Bias

A great deal of skepticism was expressed by participating institutions as to whether any review process could systematically demonstrate that bias had or had not occurred. Some institutions likened this type of an analysis to what is currently required in response to research misconduct allegations under the

Office for Research Integrity (ORI) regulations,¹⁹ and a couple of institutions were contemplating sending any retrospective reviews through the existing research misconduct process, reasoning that the individuals within the organization who conduct these investigations have the best experience for this review. However, most other institutions expressed resistance to approaching the retrospective review and bias analysis under the same complicated and prescriptive framework required by the ORI regulations and stated that such a process was not appropriate for this type of review. The concerns with using the research misconduct process were three-fold: (1) research misconduct investigations, even when very rare, consume substantial resources and are wholly disruptive of ongoing research; (2) such investigations are only conducted when there is a reason to suspect that misconduct has already taken place; and (3) the identification and management of financial conflicts of interests is not indicative of research misconduct and linking the two processes could conflate the two concepts, both in the institution and to the public.

As one participating institution noted, research misconduct inquiries can bring work in a research laboratory to a stand-still (another representative said that “the world stops” during the research misconduct investigation process), and in the conflicts context there would not necessarily be an actual allegation of misconduct so it seemed unnecessary to cause the same type of disruption. It was also noted that depending on how far along a given research project is, it may be extremely challenging or impossible to evaluate bias given a paucity of available data. Several participating institutions pointed out that a finding of bias does not necessarily equate to a finding of research misconduct, and to equate or replicate the research misconduct process in the financial conflicts of interest analysis could inappropriately call into question an investigator’s integrity.

One model that was developed by participating institutions during one regional meeting was a two-tiered approach, consisting of a preliminary assessment, followed by a full retrospective review only if certain criteria were met. The preliminary review would be a more cursory review that could, in some cases, conclude that a full retrospective review would be useless or unnecessary. For example, a preliminary review could find that a research activity was in such a nascent state that no bias could be detected by any review process (e.g., if the research is in a planning stage or the review occurs before many data points have been collected). By keeping a preliminary review at a much higher level than the ORI-required process it still would be possible to review the research for any glaring concerns and explain any limitations in the determination of bias and any corrective actions that might be warranted.

Many of the participating institutions that considered this two-tiered review model agreed that it could potentially save substantial time and decrease unnecessary burden. However, some institutions felt that the type of information and the expanse of data that would need to be reviewed in order to make even a preliminary judgment about the possibility of finding bias might require a process similar to a research misconduct investigation. It is also worth noting that the bar for finding an FCOI is high (that the significant financial interest could “directly and significantly” affect the design, conduct, or reporting of the PHS-funded research). Therefore, if that standard for an FCOI has been met (which is a prerequisite to conducting a review that might uncover bias), it is important to evaluate carefully and document the reason for the finding when a preliminary review concludes that a full retrospective review is unwarranted. Although not entirely inconsistent (a significant financial interest might be found to have the ability to directly and significantly impact the research, thus leading to the conclusion that an FCOI exists, but on preliminary review the available data show no sign of any impact having

¹⁹ 45 CFR Part 93.

actually occurred), institutions may need to address the possibility of tension between these two standards.

As for whether bias could ever be determined, it was suggested that one metric sometimes used is to look at publications and other results of the research, if available; however, it was noted that those will only be an indirect measure and that it really may not be possible to prove that science was in fact biased. Further, publications and results may not be available until after the research has concluded. Other possible metrics discussed included reviewing enrollment (were inclusion and exclusion criteria met), looking at systematic protocol deviations for irregularities that might indicate that scientific integrity was undermined, and assessing whether the design of the study was suspect for any reason. It was also suggested by a participating institution that one of the best ways to learn whether bias may have occurred would be to interview the research staff who had the confidence of the conflicted investigator to probe whether any intentional or unintentional instances of overinterpreting or misinterpreting data had occurred. This might be done in person, or by circulating a letter inviting individuals to come forward with any indications of bias. Other institutions felt this might undercut the trust within a laboratory and risk inadvertently triggering the full research misconduct process.

At least one institutional representative noted that they were strongly considering charging individual departments for the cost of a retrospective review, if one is required, because of the resources that will be involved for this type of a review. The point was also made that if investigators are well educated on this aspect of the new rule and understand that the potential penalty for failing to timely disclose an FCOI is something similar to a research misconduct process (that their departments might be asked to fund) that will provide strong incentive for timely compliance.

Mitigation Reports

Several institutions felt that the approach to mitigation should be essentially the same as what would be done prospectively had the FCOI been identified at the appropriate time (e.g., whatever the management plan would have been should now be implemented as a mitigation plan). Some institutions appeared to conflate the mitigation plans with the retrospective review and bias determination, and it was noted by others that these are separate processes and that the mitigation plan and report is only required once bias has been found. Some participating institutions stated that a mitigation plan may look a lot like prospective management implemented at a later stage, although it should be noted that there may be actions required given the bias finding that would not have been necessary if prospective identification of an FCOI had occurred. The need for a case by case analysis of when additional actions (such as third party data analysis or retroactive notification on publications or presentations) supports having a written policy that allows for flexibility in the institutional response.

VI. Public Accessibility of Identified Financial Conflicts of Interest

Regulatory Requirement

The new rule mandates public access to individual investigators' FCOI information in keeping with its emphasis on increasing transparency. Institutions have two options to comply with the public accessibility requirement: (1) publishing certain FCOI information on a publicly accessible web site; or (2) providing a written response to any request for that FCOI information within five business days of the request. The relationships that must be made public include FCOIs that were disclosed and continue to be held by senior/key personnel of the project. The information that an institution must make publicly available includes, at a minimum: the investigator's name; the investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest, which may be reported in ranges (\$0-\$4,999; \$5000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.²⁰

Institutional Concerns and Proposed Approaches

Most participating institutions were undecided as to which of the two approaches they would adopt, but spent significant time at the regional meetings discussing the advantages and drawbacks of each. Almost all participating institutions who do not already publicly report individual financial interest information indicated that as of the end of 2011 no firm decision had been made as to which method they would use to make the information publicly available. However, many noted that they were leaving the meetings with broader perspectives than when they had arrived and noted that preliminary decisions on this issue would be subject to review after the rule had been in effect for some time to assess the burden and effect of whichever method is chosen.

The advantages to each of the available options for public accessibility to FCOI information that were cited by participating institutions are described in more detail below and include the following:

- Advantages of maintaining a publically accessible website
 - Positive responses from the public, media, and government to current websites with financial disclosures
 - Improved quality of disclosures from investigators whose information is readily available for review
 - No human resources needed to respond to individual requests
 - Context and messaging can be provided and coordinated between institutions
- Advantages of responding to individual requestors
 - Ability to tailor information provided to address the request
 - No resources needed to develop and maintain a website
 - For those who elect to apply the public accessibility requirement to PHS-funded researchers only, avoiding singling out the financial interests of PHS-funded investigators
 - Ability to catalogue the nature and number of requests for information

²⁰ 42 CFR § 50.605(a)(5)(i).

Specific Discussion Topics

Maintaining FCOI Information on a Publicly Accessible Website

Those institutions that have already chosen to disclose certain financial information or industry ties for all faculty on a website made a strong case for the benefits of developing such a site, including the incredibly positive response from the public, patients, the government and media coverage. Those institutions also noted that the fact investigators know that information will be made public and potentially evaluated improves the quality of the information they receive through the investigator financial disclosure process. Additionally, once the financial interest information is published, investigators tend to review their data and that of their colleagues, serving as a further accuracy check.

Several institutions remarked that responding within five days may prove challenging depending on the volume of requests; it was expected by many that media outlets and advocacy groups would likely make broad sweeping requests for information in an effort to “catch” investigators in factual discrepancies, as opposed to physician-specific or project-specific requests by patients or research subjects with a personal interest in the information. It was noted, however, that although requests may begin the day after the new rule becomes effective on August 24, 2012, there will arguably be nothing to report on that day assuming that the policy has just gone into effect because the only information required to be provided is information related to FCOIs as determined under the process required by the new rule.

Participating institutions also suggested that a website provides the ability to contextualize the information and present it from the institution’s and investigator’s perspective. Representatives discussed including in the public website a general description of the conflicts review and management process at the institution to provide patients and the broader public a sense of what the data on the website signify. It also is a forum in which institutions can describe the positive nature of partnerships with industry so that patients and subjects can understand the benefits that derive from these collaborations. Several institutions noted that they encouraged collaborations with industry and did not want to appear ashamed of those same relationships when reported as FCOIs. More than one institution mentioned that if they believed the reported financial relationships as managed could do harm to patients, subjects, or the integrity of research data, the institution would not allow such relationships to occur.

For those considering the public website option, it was discussed whether it might be feasible, and powerful, for all PHS-funded institutions to post simultaneously on August 24, 2012 an identical or very similar educational message on their websites describing the benefits to patients and the scientific enterprise of principled partnerships with industry and the importance of the process of conflict identification and management. Many institutions agreed that such a statement would be beneficial to their institution and to the public trust, and indicated that such an effort might make them more likely to choose the website option. It was suggested that AAMC develop such a statement with the assistance of AAMC member institutions and broadly disseminate the statement for voluntary adoption.

The point was made that the category of “key personnel” for which public accessibility is required is a smaller subset than the investigators from whom the institution is required to obtain disclosures; some institutions stated that they might focus on that definition and try to reduce the number of individuals for whom information is made public. Certain institutions discussed having two separate webpages, one for general financial interest or industry relationship information for all faculty clinicians and a separate one with the specific information required by NIH for PHS-funded researchers; this was in part motivated by

the fact that there may be “key personnel” who are not faculty. Others contemplated only making information public for PHS-funded researchers, but expressed concerns that this could lead viewers to the misimpression that only federally-funded investigators (and not investigators whose research is entirely supported by industry) have financial conflicts of interest. Several institutions planned to connect the new required information to existing faculty web-pages to give the information about industry ties context within a faculty member’s entire profile and professional biography; this has been the approach taken by some institutions that have already developed such sites.

Responding to Individual Requestors

For some participating institutions, the concept of reporting FCOI information on a publicly accessible website appeared at first to be a non-starter, in part because of the perceived amount of work and resources to establish and maintain such a website, but also due to a sense of vulnerability about putting out this information. Of particular concern was the fact that other public sources of similar information (for example, the industry-reported data compiled by ProPublica and the eventual publication of the Centers for Medicare and Medicaid Services’ database of all payments made by manufacturers to physicians and teaching hospitals²¹) will inevitably be inconsistent due to different reporting metrics and timeframes. Additionally, some institutions feared that faculty members would view a public report as an invasion of privacy by the institution or as a spotlight on those investigators with PHS funding, and worried that such impressions might put institutions and their faculty in an adversarial position.

For those institutions considering responding within five days, it was suggested that institutions define by policy when the five day period begins, because if it is the date of the request itself (as indicated on the letter) then the institution might be in violation of the regulations before the correct person at the institution ever receives the request. One institution suggested establishing by policy that the institution is required to respond within five business days from when the COI office receives the request, and set forth that policy clearly on-line so that requesters are aware to whom requests for information should be made and the time-frame within which the institution will respond. Another suggestion was to develop a web form for such requests that must be used, so that the institution is sure to have received all the information it needs to respond to the request and is alerted to requests received through this centralized web-based process. It was pointed out, however, that the purpose of these requirements is to make it easier for patients, families, and potential research subjects to get relevant information. If institutions make the process too difficult or prescriptive, the institution’s commitment to transparency and public accessibility could be questioned.

Some institutions noted that as with a website, individual responses could provide context for the information. These institutions expressed concern that if the information was just pulled randomly from a website there would be no opportunity for the institution to provide appropriate and specific context for the information, whereas a response letter arguably provides that avenue. One institution discussed developing informational and educational material that would be shared along with any response to a request for information to contextualize the response further, and several other institutions indicated an interest in doing the same.

²¹ Known as the “Sunshine” rule, Section 6002 of the Affordable Care Act sets forth the requirements for manufacturers to report all payments or transfers of value to physicians and teaching hospitals. A proposed rule implementing the provisions was published by CMS December 19, 2011. The first data, covering payments made in 2012 but beginning some period after publication of the final rule, will be publicly available in September 2013.

Until the new rule is fully implemented, the volume of requests for information or the number of visitors to individual institutional websites will be unknown. Some institutions expressed the belief that there would be an eventual public expectation, even if there was no regulatory requirement, that FCOI information would be available on every institution's website.²² Other institutions were planning to wait for a year, see how many requests they received and the nature and breadth of such requests, and then determine whether moving to the website option made more sense.

²² More than one institution noted that the inclusion of the five day response option in the final rule was seen by many as a compromise on the part of the Department of Health and Human Services and that federal officials and the media might view the individual response option as “less transparent” than a website.

VII. Collecting and Considering Information About Travel

Regulatory Requirement

The information institutions must collect in the review of significant financial interests under the new rule now includes most travel taken by investigators. This represents a significant addition to the information currently disclosed to institutions. Although investigators are not required to disclose the value of the travel, this requirement is included within the definition of significant financial interest. In addition to the specific categories of financial interests expressly included and excluded from the definition of significant financial interest, the definition contains a separate sub-section (2) that states “Investigators also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education..., an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.”²³ An institution’s FCOI policy is required to specify the details of what must be disclosed with respect to travel, including at a minimum “the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.” It is then up to the institution to determine whether additional information must be sought, including specific valuation of the travel, to “determine whether the travel constitutes an FCOI with the PHS-funded research.”

Institutional Concerns and Proposed Approaches

Participating institutions expressed substantial anxiety over the collection and review of travel information. There was some confusion expressed regarding the implications of this section of the significant financial interest definition and the apparent plain meaning that *all* travel information, regardless of circumstance or value, constitutes a significant financial interest, and an institution must determine whether it is “related” to the research and, if so, rises to the level of an FCOI. A few institutions suggested that while investigators are required to disclose all travel under the new rule, the value of such trips may be evaluated as “remuneration” covered by the first section of the definition and subject to the \$5,000 de minimis threshold. Statements from NIH representatives in public meetings and the placement of the travel provision in the definition of significant financial interest supports the former interpretation (that all covered travel, regardless of value, should be disclosed as a significant financial interest), but the levels of concern about this provision warranted the discussion of this implication at each of the AAMC working meetings.

For many institutions, the primary concern related to travel is a data management issue, and a fairly significant one at that. Institutions will need to develop a reasonable approach to collecting the information required by the regulations, but as a practical matter this information should not needlessly increase the number of FCOIs under management by an institution’s COI committee. Many participating institutions surmised that NIH’s main interest in requiring that this information be collected is to ensure that institutions are aware of their faculty travel and any excessive situations that raise concerns. Therefore, institutions were motivated to develop reasonable approaches to the collection and

²³ 42 CFR § 50.603.

evaluation of this information to identify any egregious circumstances without undermining the entire conflicts management process by over-resourcing this particular issue. Discussions centered around the following issues, which are described in greater detail below:

- Collecting travel information, through existing or new disclosure systems
- How institutions should consider travel information in the FCOI analysis process, including creating thresholds or pre-defined “red flags” for review, when to involve department chairs or other administrative processes, and when a COI committee should receive information about travel
- The advantages and drawbacks to requiring that all travel be arranged through the institution
- Creating policies about the timing of reporting travel and when travel might be “new” information

Specific Discussion Topics

Collecting Travel Information

Certain participating institutions were already collecting information related to sponsored or reimbursed travel, and many of these are asking for the types of information required by the new rule (purpose, sponsor, destination, duration). Those that have historically considered travel-related expenses as “income” from a company tend to require investigators to determine and provide value estimates in order to add them to the aggregated financial interests. These institutions indicated that they are re-thinking that approach given the fact that the new rule does not require the collection of specific value amounts related to travel and appears to apply to all travel interests without any de minimis value threshold, particularly given the amount of time such fact-development takes for COI committees.

From a process perspective, certain institutions had incorporated the review of travel information through an on-line collection tool. One institution with a particularly sophisticated electronic collection tool stressed that the collection of this information is burdensome even with their system; furthermore, notwithstanding their system, the representative was fairly confident that they were nowhere near achieving 100% compliance.

As with other aspects of the new rule, certain institutions reported giving serious thought to limiting the collection of travel-related significant financial interests to PHS-funded researchers only, given the particular burden the collection of this information may pose. However, it was noted again by others that this might unfairly stigmatize and burden PHS researchers when institutions want to foster and encourage individuals to seek these grants. Another approach to limit the reach of the travel requirements that was discussed would be to impose a restrictive policy where gifts, including travel, are not permitted except in certain limited identified situations (such as reimbursement for travel associated with CME programs or other association meetings, in connection with an approved consulting arrangement, required in connection with Principal Investigator responsibilities, etc.). Disclosure would be required in those limited circumstances where travel payments are permitted so that an FCOI analysis could be performed.

Considering and Evaluating Travel Information

Many institutions contemplated setting a fairly high bar before travel-related payments would trigger the FCOI definition; therefore, although the requirements related to travel information would significantly

impact investigator disclosure obligations and potentially the institution's responsibility to review such disclosures, it may be an unusual occurrence for travel to be considered an FCOI. Several institutions alluded to a presumption that most travel related to PHS-funded research will not "directly and significantly affect the design, conduct, or reporting" of the research. As such, the management obligations with respect to such information would not increase significantly. That said, there were institutions who acknowledged that under their current policy their COI committees have found an FCOI and imposed management plans based on travel information alone; these institutions took the position that these analyses will always be fact specific and it is difficult to say across the board that paid travel, or even paid travel valued below a certain amount, is never a conflict.

In general, there was support for developing broad, non-prescriptive policies or procedures regarding when a travel disclosure warrants additional review and diligence by the institution or might suggest that the paid travel meets the definition of an FCOI. However, various factors were identified as being potentially concerning trigger points that might encourage further diligence by the institution, such as travel outside the United States or travel to an "exotic" or "luxurious" location. Such factors may cast too wide a net or miss truly worrisome travel; it was recognized that some public health research may involve travel to locations that, while they may appear exotic in a disclosure of location and duration alone, are far from luxurious, and a short domestic flight to New York City for an investigator and guest for three nights in a five-star hotel with extended recreational activities could be a potential FCOI.

Institutions noted that the goal of any defined trigger points would be to identify those situations where additional compensation is being disguised through travel compensation. Throughout the working meetings potential "red flags" for review of travel disclosures included the following:

- International travel
- Inclusion of an investigator's spouse or family (although this information is not required to be collected, an institution could ask for it)
- Travel that is unnecessary (in terms of location, duration, or scheduled recreational activities) given the ostensible business purpose of the trip
- Travel for a duration beyond a set timeframe or estimated to be valued over a certain defined threshold
- Many trips for one company in a defined timeframe

Many institutions discussed the possibility of utilizing department chairs as the central gatekeepers for managing travel information, in part to avoid over-burdening the COI committees with this category of information and because department chairs often play a role in approving faculty travel plans. A few suggested that they anticipated using a process that relies almost exclusively on the department chair, as the institutional official's designee, to evaluate potential travel and either approve it or disapprove it, without a more formalized FCOI determination by the COI committee or regular COI process. Concerns were expressed that this may not be a sufficient or an appropriate delegation because the department chair may not have information regarding an investigator's complete financial interest portfolio to determine whether the requested travel payment is reasonable or whether it tips the balance to suggest an FCOI might exist. If the institutional official is going to delegate this type of review to the department chair, several institutions felt it was worth considering whether there needs to be a mechanism to ensure that the department chair has access to other financial disclosure information, or whether it is sufficient that the department chair is merely charged with reviewing travel disclosures. Other institutions contemplated a slightly different approach whereby the department chair would serve

as the screen for any concerning travel payments and, if flagged as problematic, refer the travel payment information to the established conflicts review process to be considered in conjunction with other existing data points.

There was no consensus among participating institutions on bright line rules for when paid travel might constitute an FCOI. For example, would it be a potential FCOI if a company pays the expenses for an investigator to stay in Paris through the weekend following speaking at a three-day conference? Some institutions felt that was completely inappropriate and might rise to the level of being an FCOI. Others felt that the length of the trip and how grueling a quick turn-around to Europe would be are relevant considerations that might justify such an expenditure on a faculty member's behalf.

Additional Considerations

Although it was suggested at several of the working meetings that a potential work-around would be to require faculty to make all travel arrangements through the institution and have all company reimbursements for travel run through the institution, it was noted that this would not address the issue of sponsored travel (e.g., where a company pays directly on behalf of a faculty member), unless institutions are able to negotiate with companies to run the travel through the institution. Many institutions felt it would be nearly impossible to achieve this on a consistent basis.

One open issue which many participating institutions raised is whether new travel related to their institutional responsibilities that may arise during the course of an ongoing project will constitute a "new" significant financial interest, in which case the institution has only sixty days to review the disclosure, determine whether it is "related" to the PHS-funded research, and perform the FCOI analysis. Several institutions noted the logistical challenge of such an interpretation, given the sheer number of paid or reimbursed trips faculty take that may be related to their institutional responsibilities.

VIII. Additional Issues – Subrecipients and Training

In addition to discussing the main changes to institutional responsibilities described in the previous sections, the discussions also turned to two other concerns raised by the new rule, subrecipients of grants and training of investigators.

Issues Related to Subrecipients of PHS Grants

The new regulations explicitly require prime awardees that carry out PHS-funded research through subrecipients to “take reasonable steps” to ensure that the subrecipient complies with the new rule. This must be accomplished by

- (1) establishing the following terms as part of the sub-award agreement:
 - (i) whether the subrecipient will comply with its own FCOI policy or the policy of the prime awardee,
 - (ii) certification from the subrecipient that its policy, if applicable, complies with the new rule (or, if such certification cannot be made, that subrecipient investigators are subject to the prime awardee’s policy with respect to disclosing significant financial interests that are directly related to the subrecipient’s work for the prime awardee),
 - (iii) if the subrecipient’s policy applies, specification of the time period(s) for the subrecipient to report all identified FCOIs to the prime awardee, which shall be sufficient to enable the prime awardee to provide timely reports to PHS under the regulations,
 - (iv) or, if the subrecipient investigators must comply with the prime awardee’s policy, specification of the time period(s) for the subrecipient to submit investigator disclosures of significant financial interests to the prime awardee, which shall be sufficient to enable the prime awardee to perform the review, management and reporting required by the regulations; and
- (2) providing FCOI reports to PHS regarding all FCOIs of all subrecipient investigators consistent with the requirements of the new rule (i.e., prior to expenditure of funds and within 60 days of any subsequently identified FCOI).²⁴

Several institutions raised concerns about how to implement effective monitoring of subrecipient compliance, particularly with respect to community physician investigators who own their own practices and are otherwise unaffiliated with a larger institution. Late in 2011, this was an area where institutions were still struggling to determine what their approach and best practices would be, both with respect to whether they would require subrecipients to comply with their policies or permit the subrecipient to rely on their own, and also with respect to how they would ensure sufficient monitoring of subrecipient compliance. Across all the working meetings, participating institutions expressed concerns that they had not come up with proposed methods for dealing with subrecipients, and were looking forward to additional conversations with colleagues and guidance from NIH on the expectations and what will become community standards on the approach.

²⁴ 42 CFR § 50.604(c).

Training of Investigators

The new rule requires institutions to ensure that, prior to engaging in covered research and at least every four years, investigators are trained on the regulations, the institution's financial conflict of interest policies, and the investigator's responsibilities to disclose significant financial interests. Additionally, investigators must be trained immediately under the following circumstances:

- (i) the institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of investigators;
- (ii) an investigator is new to an institution; or
- (iii) an institution finds that an investigator is not in compliance with the institution's FCOI policies or management plan.²⁵

Certain institutions reported that they have already implemented targeted intensive education for departments and chairs; others noted that their current educational programs were in response to specific issues related to conflicts of interest that had received media attention, so they were more reactive corrective actions than preventative training programs. Several institutions noted that it would be helpful to have a sense of the content of training being given to NIH program officers as this would serve as a useful model for training on the basic requirements of the rule.

Going forward, many institutions noted that they planned to use the CITI Program COI training module that is being revised to reflect the requirements of the new rule. A few institutions mentioned using HealthStream as a training tool, although they were not certain whether they would be using a COI module, or if it was available. Others discussed the possibility of leveraging programs that had already been developed or are under development by individual institutions, which had agreed to make them available and accessible to other institutions to avoid duplicating efforts. Additionally, NIH has published a web-based training module on the new rule that could be of use to institutions in developing their internal training programs.²⁶ Prior to the publication of the NIH training materials, many institutions indicated that they believed the NIH training materials would be a helpful baseline in teaching investigators the text of the regulations, but were not sure whether the agency would be able to provide extensive context and examples in the training material out of concern that too much additional material would be considered official agency guidance.

It was recognized by many institutions that an effective mechanism for tracking compliance with the training requirements as a condition to receiving grant funding would be necessary; some discussed the possibility of building that into an electronic system such that the sponsored research office would be able to certify whether a certain individual had completed an on-line training module prior to awarding the funds.

Many institutions reflected that they would likely incorporate any required COI training into already existing mandatory research training programs applied across the board at their institutions, as opposed to limiting it to PHS-funded researchers. However, a select few institutions noted that they were considering requiring training on the new COI rule only for PHS-funded investigators. A few institutions contemplated tying training to the disclosure process; to the extent an investigator is required to disclose a significant financial interest, that electronic disclosure process would incorporate a training

²⁵ 42 CFR § 50.604.

²⁶ Available at: <http://grants.nih.gov/grants/policy/coi/>.

component. Other institutions similarly mentioned using the “ClickCommerce” software as a mechanism to capture training in one location.

Regarding the timing of by when training must have occurred, it was noted by some that the FAQ on training published by NIH is unclear on this point. The FAQ notes that once an institution’s COI policy is implemented, investigators are expected to receive training prior to engaging in NIH-supported research “or by the issue date of the Notice of Award issued subsequent to the Institution’s implementation date.” It was therefore concluded by some that training all of an institution’s investigators prior to August 24, 2012 (assuming that institutions wait until the required implementation date and do not post their policies prior to that point) is not necessary; however for any investigators that are engaged in ongoing NIH-funded research, they would need to receive training in order to continue with that work uninterrupted. For any other investigator receiving awards after the implementation date, training would need to occur prior to issue date of the Notice of Award for that funding. And again, to the extent a new investigator joins an institution, such individual would need to be trained “immediately,” a concept that can be further defined by institutional policy and on which there is some flexibility.

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