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# Federal Financial Conflict of Interest Rules and Biomedical Research: A Legal Overview

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## Summary

Every year the federal government through a host of different agencies spends billions of dollars supporting *biomedical* research. In addition, the federal government, through the Food and Drug Administration (FDA), continually reviews the biomedical research that supports an application to market certain products, like drugs or medical devices. Collectively, the various federal agencies that either support or oversee biomedical research have a strong interest in ensuring that the underlying research is scientifically rigorous and free of bias. However, if a biomedical researcher has a conflict of interest—that is, a real or potential incompatibility between one’s private interests and one’s public or fiduciary duties—that conflict, including a financial conflict, could bias the research or at the very least undermine the credibility of the researcher’s conclusions.

To prevent such financial conflicts of interest (FCOIs) from undermining government-supported or -regulated biomedical research, the relevant government agencies have established an often-complex set of regulations and policies governing the identification and management of financial conflicts as they relate to biomedical research. The primary federal agency that funds biomedical research is the Department of Health and Human Services (HHS). Within HHS, the Public Health Service (PHS) oversees the 11 operating divisions of HHS that provide research grants and cooperative agreements. When funding is granted to an individual, private organization, public or private university, or other institution by any of the 11 funding agencies, the grantee institution must follow the PHS rules for “objectivity” in research.

The PHS objectivity rule provides that individual researchers must disclose “significant financial interests.” A financial interest is “significant” if the interest exceeds the minimum threshold outlined under federal regulations *and* the interest “reasonably appears to be related” to the responsibilities of the researcher as dictated by the policies of the researcher’s institution. If both of those requirements are met and a researcher has a “significant financial interest,” the researcher must disclose the significant financial interest to his institution’s designated official. The institution, in turn, must make a determination of whether the significant financial interest amounts to a FCOI. Such a determination is made by looking to whether the disclosed interest “relate[s] to the PHS-funded research” and, if so, whether the interest “could *directly and significantly*” affect the design, conduct, or reporting of the PHS-funded research. If the institution determines that a potential FCOI does exist, the institution must follow federal regulations to proactively address and manage a financial conflict.

Beyond the PHS objectivity rule, other federal rules respecting FCOIs and biomedical research exist, as well. For example, the HHS Common Rule may be applicable when an institution uses federal funds to conduct biomedical research involving human subjects. The Common Rule, by mandating that research institutions employ Institutional Review Boards (IRBs) to oversee human subject testing, have provided IRBs with the potential to scrutinize the effect of FCOIs on a particular research project. Moreover, the FDA has its own version of the Common Rule and a distinct set of regulations requiring a separate review of financial interests before certain products can be marketed. Importantly, covered applicants must disclose financial interests to the FDA even when no federal funds are used in the research and development of a product. Agencies outside HHS also fund biomedical research, albeit on a somewhat smaller scale. Most, but not all, of those agencies follow rules similar to the PHS objectivity requirements and Common Rule. This report summarizes the standards for disclosing financial interests for an institution conducting research funded by the National Science Foundation and the Department of Defense.

Finally, this report concludes by discussing recent administrative and legislative developments with respect to the law regarding FCOIs and biomedical research.

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## Introduction

A significant portion of the more than \$50 billion the federal government spends annually on research projects supports *biomedical* research.<sup>1</sup> And a host of different government agencies—primarily those housed within the Department of Health and Human Services (HHS)—financially support biomedical research.<sup>2</sup> In addition to directly supporting certain biomedical research projects, the government—primarily through the Food and Drug Administration (FDA)—continually reviews the biomedical research that is used to support an application to market certain products, like drugs or medical devices.<sup>3</sup> Collectively, the various federal agencies that either support or oversee biomedical research have a strong interest in ensuring that the underlying research is scientifically rigorous and free of bias.<sup>4</sup>

If a researcher has a conflict of interest—that is, a real or potential incompatibility between one’s private interests and one’s public or fiduciary duties<sup>5</sup>—that conflict, including a financial conflict, can potentially undermine the research.<sup>6</sup> For example, a researcher employed by a university might be paid a consulting fee from a private company to help the company analyze the results of a clinical trial for an experimental cancer drug that the company hopes to one day market. At the university, the researcher might also be participating in a similar clinical investigation that is funded by a grant from the National Institutes of Health. In such a case, the researcher might feel pressured to analyze the university research in a way that enhances his standing with the pharmaceutical company in the hopes that he will be offered opportunities to consult with the pharmaceutical company in the future. As a result, a potential conflict may exist that could bias the research or at the very least undermine the credibility of the research.

To prevent such financial conflicts of interest (FCOIs) from undermining government supported or regulated biomedical research, the relevant government agencies have established an often-complex set of regulations and policies governing the identification and management of financial

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<sup>1</sup> For example, according to the National Science Foundation (NSF), 56% of all federal research obligations in FY2009 went to the Department of Health and Human Services (HHS) for which the majority was used for medical research. See *Science and Engineering Indicators 2012*, NATIONAL SCIENCE FOUNDATION 33-35 (Jan. 2012), <http://www.nsf.gov/statistics/seind12/pdf/c04.pdf>. In a report from September of 2013, the NSF noted that for FY2011, of the 53.7 billion dollars spent on basic and applied research, HHS received 53% of all federal funding. See Michael Yamaner, *Federal Funding for Research Drops by 9% in FY2011*, NATIONAL CENTER FOR SCIENCE AND ENGINEERING STATISTICS: INFOBRIEF 1 (Sept. 2013), <http://www.nsf.gov/statistics/infobrief/nsf13336/nsf13336.pdf>. Biomedical research may include clinical trials for pharmaceuticals, development of medical devices, or experiments in medical biotechnology. Biotechnology generally refers to anything that applies biological processes to develop products or resources. In the medical context, biotechnology applies technological or engineering principles to biological processes to address human health issues and diseases. See *National Institute of Biomedical Imaging and Bioengineering*, NATIONAL INSTITUTES OF HEALTH <http://www.nibib.nih.gov/research/featured-programs/biomedical-technology-resource-centers>.

<sup>2</sup> See Mark Barnes and Patrik S. Florencio, *Looking Beyond the Academic Medical Center: Investigator, IRB, and Institutional Financial Conflicts of Interest in Human-Subjects Research: Past, Present and Future*, 32 SETON HALL L. REV. 525, 531–32 (2002). Research funding in various scientific fields is generally awarded through grants and cooperative agreements on a case-by-case basis and is administered through Grants.gov. GRANTS.GOV, <http://www.grants.gov/web/grants/home.html>.

<sup>3</sup> See 21 C.F.R. pt. 54.

<sup>4</sup> See Sally J. Rockey and Francis S. Collins, *Managing Financial Conflict of Interest in Biomedical Research*, Vol. 303, No. 23 JAMA, pg. 2400.

<sup>5</sup> See BLACK’S LAW DICTIONARY (9<sup>th</sup> ed. 2009) (defining “conflict of interest.”).

<sup>6</sup> See, e.g., Bryan A. Liang & Tim Mackey, *Confronting Conflict: Addressing Institutional Conflicts of Interest in Academic Medical Centers*, 36 AM. J. L. AND MED. 136 (2010).

conflicts as they relate to biomedical research. This report provides a legal overview of the current federal requirements regarding FCOIs held by any investigator who participates in biomedical research funded or otherwise regulated by the federal government. In particular, the report focuses on the HHS requirements, as those requirements are the most widely applicable to medical research.<sup>7</sup> Nonetheless, the requirements of other federal agencies that often fund or regulate research, such as the FDA, the National Science Foundation, and the Department of Defense, are also discussed. This report concludes with an overview of the current developments with respect to the law governing FCOIs and biomedical research.<sup>8</sup>

To guide the discussion that follows, **Table 1** provides a brief synopsis of the various federal regulations on FCOIs and biomedical research.

**Table 1. Summary of Agency Requirements for the Disclosure of FCOIs**

Agency	Statute/ Regulation	Applicability	Disclosure Threshold	Conflict Criteria	Institutional Requirements
Health and Human Services (HHS) General Objectivity Requirements	42 C.F.R. pt. 50	Each Institution that is applying for or receives Public Health Service (PHS) research funding (via a grant or cooperative agreement)	Generally: (1) Interests in excess of \$5,000; (2) reasonably related to Institutional responsibilities	“Directly and significantly” affects the design, conduct, or reporting of the research	(1) FCOI determination; (2) management plan; (3) continued monitoring; (4) annual reporting by grantee IRB
HHS “Common Rule”	45 C.F.R. pt. 46	All HHS agency funded research involving human subjects and all other agencies that have adopted the rule	No express disclosure threshold	Broad authority left to IRB; focus on “informed consent”	(1) Written assurance to agency; (2) continued monitoring
Food & Drug Administration (FDA) Rules on the Protection of Human Subjects and IRBs	21 C.F.R. pt. 50 & pt. 56	Generally, all FDA-regulated clinical trials	No express disclosure threshold	Broad authority left to IRB; focus on “informed consent”	(1) No written assurance required; (2) Agency may waive IRB review entirely

<sup>7</sup> See *supra* note 1.

<sup>8</sup> Outside of the context of the FDA’s FCOI regulations, this report does not address issues related to financial conflicts of interest in purely privately funded biomedical research. In addition, discussions about FCOIs and government employees and FCOIs and physicians are outside the scope of this report. For a discussion of these topics, see CRS Report R43365, *Financial Assets and Conflict of Interest Regulation in the Executive Branch*, by (name redacted) and also CRS Report RS22743, *Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview*, by (name redacted).

Agency	Statute/ Regulation	Applicability	Disclosure Threshold	Conflict Criteria	Institutional Requirements
FDA FCOI Rules	21 C.F.R. pt. 54	FDA marketing applications for products intended for human use	(1) Interest affected by application result; (2) equity interest in the sponsor (generally >\$50,000); (3) Intellectual property in the product; or (4) direct payment from sponsor (>\$25,000)	FDA determination based on: (1) reliability of the study; (2) impact on research-design; (3) Institution's mitigation plan	Institution submits: (1) names of all Investigators; (2) certify that no prohibited financial arrangements exist
National Science Foundation (NSF)	Grantee Policy Manual § 510	All NSF-funded research or educational programs	Generally, interests in excess of \$10,000	“directly and significantly affect the design, conduct, or reporting” of the research	Institution must impose “conditions and restrictions” for any conflict; unless “ineffective or inequitable”
Department of Defense (DOD)	General Application Instructions	All research funded through the Congressionally Determined Medical Research Programs (CDMRP)	No express disclosure requirement	Defer to Institution's existing policy	Defer to Institution's existing policy

**Source:** Created by CRS.

**Notes:** **Table I** summarizes the federal requirements for the disclosure of financial conflicts of interests for the agencies that most often fund biomedical research. **Table I** lists the agency name in the far left column. “*Statute/Regulation*” refers to the applicable section of the Code of Federal Regulations or agency policy. “*Applicability*” describes the types of research within the scope of the requirement for that agency. “*Disclosure Threshold*” refers to the minimum value or criteria necessary to require an investigator to disclose a particular interest. “*Conflict Criteria*” is the test by which the Institution or agency evaluates whether a disclosed interest rises to the level of a conflict. “*Institutional Requirements*” are any other requirements applicable to the Institution applying for the research funds beyond the conflicts determination.

## HHS Requirements for FCOIs

By its nature, most federal funding for biomedical research flows from HHS.<sup>9</sup> The United States Public Health Service (PHS) is the primary division of the department that oversees grants for research funded by the eight primary agencies and three human services divisions of HHS.<sup>10</sup> Congress granted the Surgeon General authority, with the approval of the Secretary, to issue regulations necessary to administer the department.<sup>11</sup> Under that authority, HHS has promulgated rules<sup>12</sup> applicable to PHS divisions to ensure federally funded biomedical research is objective and serves the public welfare.<sup>13</sup> Institutions applying for grants from a PHS agency must establish procedures to “provide a reasonable expectation that the design, conduct, and reporting of research” will be free from bias resulting from conflicts of interest.<sup>14</sup> Some federal agencies outside the scope of PHS, but which also fund biomedical research, voluntarily follow the PHS regulations.<sup>15</sup> Further, because much of the research conducted at both public and private universities relies on federal funding, most universities have adopted conflict of interest policies that mirror, or build on, the PHS regulations.<sup>16</sup> As a result, the PHS general objectivity requirements are the most widely applicable to biomedical research, and accordingly, the PHS regulations will be discussed in more detail. To guide the discussion that follows, **Figure 1** provides a flowchart of the process by which FCOIs are identified and managed pursuant to the PHS general objectivity requirements.

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<sup>9</sup> See *supra* note 1; see generally 42 U.S.C. § 241(a) (providing the Secretary of HHS with the authority to “encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies....”).

<sup>10</sup> See generally 42 U.S.C. § 203; 42 C.F.R. § 50.602. The PHS regulations apply directly to grants from the following: (1) Administration for Children and Families (ACF), (2) Administration for Community Living (ACL), (3) Agency for Healthcare Research and Quality (AHRQ), (4) Agency for Toxic Substances and Disease Registry (ATSDR), (5) Centers for Disease Control and Prevention (CDC), (6) Centers for Medicare & Medicaid Services (CMS), (7) Food and Drug Administration (FDA), (8) Health Resources and Services Administration (HRSA), (9) Indian Health Service (IHS), (10) National Institutes of Health (NIH), (11) Substance Abuse and Mental Health Services Administration (SAMHSA). *Operating Divisions*, HHS, <http://www.hhs.gov/about/foa/opdivs/index.html>.

<sup>11</sup> 42 U.S.C. § 216.

<sup>12</sup> Hereinafter “PHS regulations.”

<sup>13</sup> 42 C.F.R. pt. 50, subpt. F.

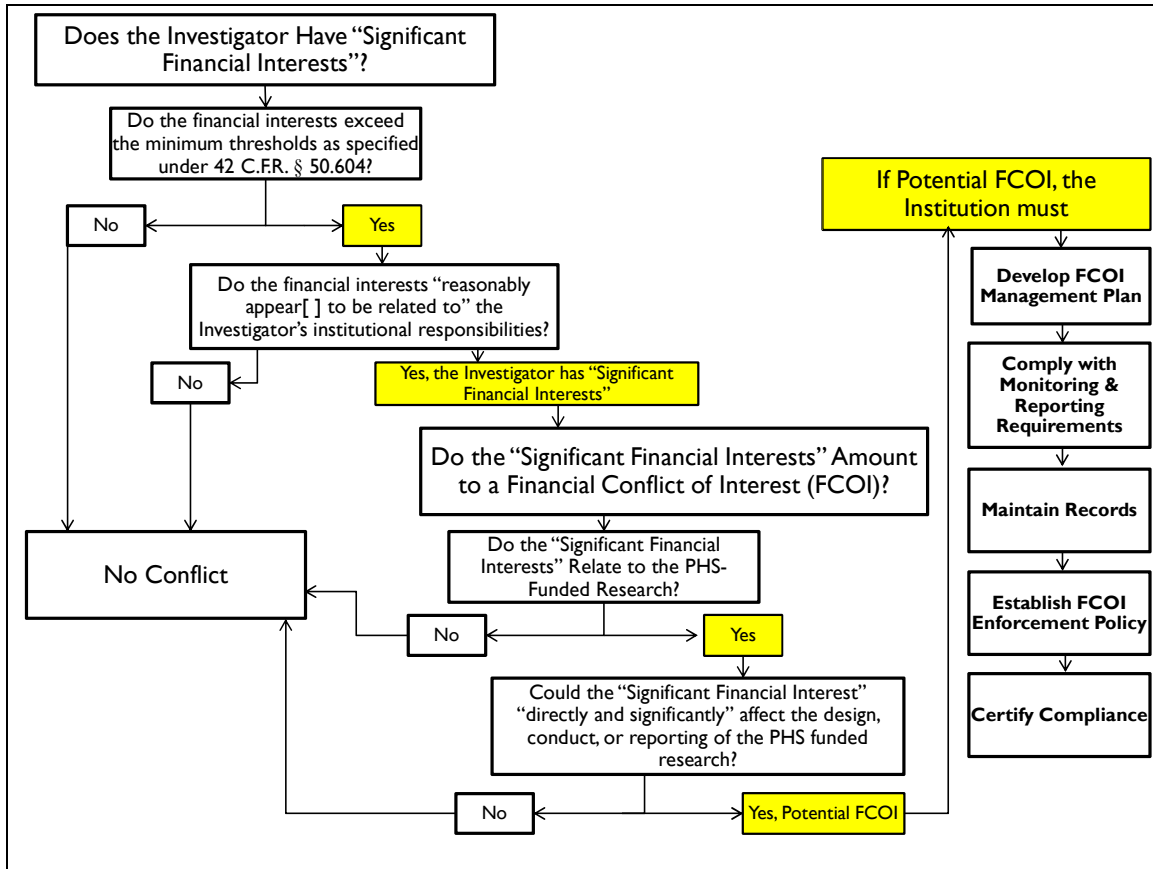
<sup>14</sup> *Id.* § 50.602.

<sup>15</sup> See *supra* **Table 1**.

<sup>16</sup> See, e.g., Univ. of Va., *Policy: Financial Conflicts of Interest for Research Investigators* (Feb. 6, 2013), <https://policy.itc.virginia.edu/policy/policydisplay?id=RES-005>; see also Harvard Med. Sch., *HMS/HSDM Policy on Financial Conflicts of Interest in Sponsored Research* (2014), available at <http://hms.harvard.edu/about-hms/integrity-academic-medicine/hmshsdm-policy-financial-conflicts-interest-sponsored-research/hmshsdm-policy-financial-conflicts-interest-sponsored-research>.



**Figure I. Summary of PHS General Objectivity Requirements**



Source: Created by CRS.

## General Objectivity Requirements for All PHS-funded Research

The PHS objectivity regulations apply to the FCOIs of “**Investigators**”<sup>17</sup> participating in research for any “**Institution.**”<sup>18</sup> An Institution is an entity that is applying for, or that receives, PHS research funding by means of a grant or cooperative agreement.<sup>19</sup> An Institution subject to the PHS regulations must (1) gather information about each participating Investigator’s significant financial interests; (2) determine whether any of those interests create a conflict that could bias the research results; (3) take steps to manage the bias, report the Institution’s findings to the funding agency, and continue monitoring Investigators through the annual reporting requirement.<sup>20</sup> An Institution must establish and maintain a written FCOI policy to ensure all

<sup>17</sup> An Investigator is defined as “the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.” 42 C.F.R. § 50.603.

<sup>18</sup> Institution means any domestic or foreign, public or private, entity or organization (excluding a federal agency) that is applying for, or that receives, PHS research funding. *See id.*

<sup>19</sup> *Id.* § 50.602. Note that these regulations do not cover conflicts arising out of federal contracts. The regulations applicable to federal contracts are found at 45 C.F.R. pt. 94.

<sup>20</sup> 42 C.F.R. pt. 50.

potential Investigators are well-informed about the federal regulations and the Institution's policy,<sup>21</sup> and the Institution must require all Investigators to complete training on the policy prior to engaging in PHS-funded research.<sup>22</sup> Further, an Institution is free to establish more stringent disclosure requirements than the federal rule requires.<sup>23</sup>

Some agencies that provide a large number of grants have created their own systems for institutions to submit the required FCOI information to the agency. For example, the NIH created the Electronic Research Administration (eRA) Commons for applicants and institutions to find funding opportunities and submit applications, which include FCOI certification.<sup>24</sup> While each grant may have unique FCOI requirements based on the individual funding opportunity announcement, the eRA Commons system allows applicant institutions to manage the reporting process in compliance with the PHS regulations.<sup>25</sup>

### Financial Disclosure by Investigators

An Institution's policy must first require that each Investigator disclose his "significant financial interests" to the Institution's designated official no later than the date of application for funds.<sup>26</sup> A financial interest is "significant" if it exceeds the minimum threshold *and* "reasonably appears to be related to the Investigator's institutional responsibilities."<sup>27</sup>

The threshold value at which an interest becomes significant depends on the source of the financial interest. The thresholds are as follows:

1. Aggregate remuneration<sup>28</sup> *and* equity interest from any *publicly traded entity* that combine to exceed \$5,000 in aggregate over the preceding 12 months.<sup>29</sup>
2. Aggregate remuneration from any *non-publicly traded entity* that exceeds \$5,000 over the preceding 12 months *or* any equity interest.<sup>30</sup>

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<sup>21</sup> *Id.* § 50.604(e).

<sup>22</sup> *See id.* § 50.604(a)–(b). The Institution must also take "reasonable steps" to ensure any subcontractors comply with the Institution's FCOI policy. *See id.* § 50.604(c).

<sup>23</sup> *Id.* § 50.604(a).

<sup>24</sup> *See* DEPT. OF HEALTH AND HUMAN SERV., NATIONAL INSTITUTES OF HEALTH, ABOUT ELECTRONIC RESEARCH ADMINISTRATION (ERA), [http://era.nih.gov/about\\_era/](http://era.nih.gov/about_era/) (last updated Dec. 9, 2013).

<sup>25</sup> *See* DEPT. OF HEALTH AND HUMAN SERV., ELECTRONIC RESEARCH ADMINISTRATION, FINANCIAL CONFLICT OF INTEREST, [http://era.nih.gov/services\\_for\\_applicants/other/fcoi.cfm](http://era.nih.gov/services_for_applicants/other/fcoi.cfm) (last updated Nov. 13, 2013); *see generally* 42 C.F.R. pt. 50.

<sup>26</sup> 42 C.F.R. § 50.604. Note that the regulations do not specify criteria for establishing a designated official to solicit and review disclosures made by Investigators. *Id.* § 50.604(d).

<sup>27</sup> *Id.* § 50.603(1).

<sup>28</sup> Remuneration includes salary or payments for services received within the preceding twelve months and equity interests; includes interest of spouse and dependents. 42 C.F.R. § 50.603. For a publicly traded entity, "equity interest" includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value. *Id.*

<sup>29</sup> *See id.*

<sup>30</sup> The primary difference between a public and non-publicly traded company is that any equity interest in a non-publicly traded company is sufficient to meet the threshold amount, whereas for a publicly traded company the combined total of any remuneration and equity interest must exceed \$5,000 to meet the threshold for disclosure. *See id.* Equity interest in non-publicly traded companies extends to interests held by the Investigator's spouse, children, or other dependents. *See id.*

3. *Intellectual property rights* upon receipt of income related to rights.
4. *Travel expenses* related to an Investigator's institutional responsibilities that are paid on behalf of the Investigator such that the monetary value is not readily known.<sup>31</sup> The disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor, the destination, and the duration.<sup>32</sup>

However, the following are *not* considered significant financial interests:

1. Salaries, royalties, or other remuneration paid if the Investigator is currently employed by the Institution.<sup>33</sup>
2. Income from investment funds such as mutual funds or retirement accounts as long as the interests are not directly controlled by the Investigator.<sup>34</sup>
3. Income from seminars, lectures, or teaching engagements from appropriate entities under 20 U.S.C. §1001(a).<sup>35</sup>
4. Income from service on an advisory committee or review panel for an entity under 20 U.S.C. § 1001(a).<sup>36</sup>

These exclusions are primarily applicable when the Institution applying for funding is also the Institution that employs the Investigator. For example, if a for-profit company were to apply for a PHS-funded research grant, an Investigator who works for that company likely would not need to disclose the existence of his retirement fund to his own employer for certification to the funding agency.

Even if a particular financial interest is above the threshold amount, the interest is only “significant,” and therefore must be disclosed, when it “reasonably appears to be related” to an Investigator's institutional responsibilities.<sup>37</sup> The Institution is required to establish a policy to guide each Investigator in determining when an interest reasonably appears to relate to an institutional responsibility.<sup>38</sup> The regulations also state that institutional responsibilities “may include, for example, activities such as research, research consultation, teaching, professional practice, [or] institutional committee memberships....”<sup>39</sup> Nonetheless, because the Investigator has the initial burden of disclosure, the ultimate decision about which interests require disclosure is left to the participating Investigator.<sup>40</sup>

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<sup>31</sup> *See id.* Disclosure does not apply to travel expenses sponsored by a federal, state, or local government agency, institution of higher education, hospital, or medical centers. *See id.* According to National Institutes of Health (NIH) guidance, an Institution may impose a *de minimis* exception for the disclosure of sponsored travel expenses up to the \$5,000 threshold for other forms of remuneration. *See Frequently Asked Questions, Grants & Funding*, NATIONAL INSTITUTES OF HEALTH (June 19, 2014), [http://grants.nih.gov/grants/policy/coi/coi\\_faqs.htm](http://grants.nih.gov/grants/policy/coi/coi_faqs.htm).

<sup>32</sup> 42 C.F.R. § 50.603.

<sup>33</sup> *See id.* This exception includes intellectual property rights. *See id.*

<sup>34</sup> *See id.*

<sup>35</sup> *See id.* Entities under this statute include federal, state, or local governments, institutions of higher education, hospitals, medical centers. *See id.*

<sup>36</sup> *See id.*

<sup>37</sup> *See id.* § 50.603.

<sup>38</sup> *See id.* § 50.604(b).

<sup>39</sup> *See id.* § 50.603.

<sup>40</sup> *See id.* § 50.604(e)(1).

The scope of an Institution's policy will dictate the Investigator's decision about which interests must be disclosed.<sup>41</sup> To illustrate, suppose the following:

**Example**

A public university applies for an extramural grant from the NIH using the eRA application procedure. The grant would fund research into tissue regeneration treatments for multiple sclerosis (MS) patients.<sup>42</sup> The university defines its institutional responsibilities as "activities within an individual's field of scientific expertise or medicine."<sup>43</sup> The university has assigned a professor in the chemical biology department to perform the research. That same professor, however, previously received monetary compensation from a large pharmaceutical company in the form of payment for the professor's travel expenses (\$100) to present at a conference about "synthetic chemistry."

To resolve whether disclosing the payments from the pharmaceutical company is required, the professor in the example must look to both the (1) federal regulations and (2) university's FCOI policy. Initially, it should be noted that, pursuant to the relevant federal regulations, there is no threshold amount under which a travel expense that "relates" to an Investigator's institutional responsibilities is *not* "significant."<sup>44</sup> Accordingly, if the Investigator determines that the conference in the example "reasonably appears to relate" to his institutional responsibilities as defined by the university, he must disclose the expense. Given the university's broad definition of its institutional responsibilities, which includes any activities within an individual's field of expertise, *any* interest that results from activities in the professor's professional capacity likely warrants disclosure. As a result, with respect to the conference in the example, it appears likely that a presentation on synthetic chemistry "relates" to the professor's field of expertise in chemical biology. Therefore, the professor in the example would likely have to disclose the travel expense he received to present at the conference.

## Conflicts Determination

After each Investigator has disclosed all significant financial interests to the Investigator's Institution, the designated institutional official or committee must *then* determine whether any of the disclosed significant financial interests is "related to" the PHS-funded research and, if so, whether the interest is a FCOI.<sup>45</sup> An interest relates to funded research if the institutional official "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."<sup>46</sup> A significant interest that relates to PHS-funded research becomes a conflict if the significant

<sup>41</sup> In the wake of the newest revisions to the PHS objectivity rules, the Association of American Medical Colleges released a report in that describes the "range of contemplated approaches" for its member institutions based on their relative size and geographic location. See ASS'N OF AMERICAN MED. COLL., IMPLEMENTING THE FINAL RULE ON FINANCIAL CONFLICTS OF INTEREST IN PUBLIC HEALTH SERVICE FUNDED RESEARCH (Mar. 2012) 1 [hereinafter AAMC REPORT], available at <https://www.aamc.org/download/277644/data/coi-rule.pdf>.

<sup>42</sup> See *OER and You: An Introduction to Extramural Research at NIH*, GRANTS.NIH.GOV, <http://grants.nih.gov/grants/intro2oer.htm>.

<sup>43</sup> An Institution may have a broad definition of institutional responsibilities within which the Investigator must determine whether the particular financial interest falls, or the Institution may provide an exhaustive list of examples from which the Investigator can assess whether the interest at issue matches. See AAMC REPORT *supra* note 41, at 3.

<sup>44</sup> 42 C.F.R. § 50.603.

<sup>45</sup> See *id.* § 50.604(f).

<sup>46</sup> See *id.*

interest “could *directly and significantly* affect the design, conduct, or reporting of PHS-funded research.”<sup>47</sup>

An Institution is responsible for developing guidelines for what the phrases “related to” and “directly and significantly affects” mean.<sup>48</sup> For example, the University of Louisville has established a Conflicts Review Board (CRB) to review “whether the disclosed interests create a conflict of interest.”<sup>49</sup> The CRB looks at the amount and nature of the interest, the timing in relation to the funded research, the likelihood of actual conflict, oversight mechanisms that are in place, the importance of the research, whether human subjects are involved, and what alternatives are available to avoid the conflict.<sup>50</sup> The University of Louisville’s criteria also illustrate how, in practice, the “related to” step is often combined with the “directly and significantly affects” step in the conflicts determination.<sup>51</sup> However, a more precise reading of the regulations suggests that there are two distinct steps of institutional review in determining whether disclosed financial interests rise to the level of a FCOI.<sup>52</sup>

At the first step in the analysis, the scope of financial interests held by the Investigator is narrower than at the initial disclosure stage because the financial interest itself must relate to the specific research being funded by the PHS agency. The focus of the institutional official at the “related to” stage is whether (1) the financial interest could change based on the research findings or (2) the entity that provided the interest has something to gain financially from the research findings.<sup>53</sup> For example, if an Investigator holds a large amount of stock in a company that could later market a medical device or drug that is the focus of the PHS-funded research, that disclosed interest would likely be “related to” the PHS research.<sup>54</sup> This is because if the research the Investigator performs proves a marketable success the stock price could increase as a result.

A more nuanced situation might be the travel expense from the **Example** discussed earlier.<sup>55</sup> If the professor in the earlier example had spoken about synthetic chemistry only in the context of AIDS research, the interest in the example would not likely be “related to” the university’s NIH-funded research about MS. Nonetheless, the professor would still need to disclose the interest at the outset because the presentation still fell within the scope of the professor’s area of general scientific expertise pursuant to the university’s policy. However, if the presentation in the example had been about new methods for treating patients with MS, then the travel expenses would be more likely to be “related to” the NIH-funded university research on MS.

If the first step is met, and the financial interest is “related to” the funded research, the institutional official must then determine whether the interest “could directly and significantly

<sup>47</sup> See *id.* § 50.603; see also *id.* § 50.604(f).

<sup>48</sup> See § 50.604(f).

<sup>49</sup> See University of Louisville, *Addressing Potential Individual Conflicts of Interest Policy and Procedures* 14–15 (2013), available at <http://louisville.edu/conflictinterest/policies/policies-folder/Addressing%20Individual%20COI%20Policy%20and%20Procedures.pdf>.

<sup>50</sup> See *id.* at 15.

<sup>51</sup> See *id.*

<sup>52</sup> 42 C.F.R. § 50.604(f); see also AAMC REPORT *supra* note 41, at 6.

<sup>53</sup> 42 C.F.R. § 50.604(f)

<sup>54</sup> See Steven Novella, *Conflict of Interest in Medical Research*, SCIENCE-BASED MEDICINE (April 23, 2008), <http://www.sciencebasedmedicine.org/conflict-of-interest-in-medical-research/>.

<sup>55</sup> See *supra* “**Example**” in subsection “Financial Disclosure by Investigators.”

affect the design, conduct, or reporting of PHS-funded research.”<sup>56</sup> For instance, even if the professor in the earlier **Example**<sup>57</sup> discloses the travel expenses and the university determines the expenses relate to the funded research, the relatively small dollar amount at issue potentially may not be enough to “directly and significantly” affect the research and, therefore, would probably not amount to a FCOI. In particular, the professor in the above example was only provided \$100, an arguably small amount especially when compared to the minimum threshold of \$5,000 to require disclosure of other interests.<sup>58</sup> Moreover, the professor’s financial interest is not likely to change as a result of the research except to the extent that he could be invited to future speaking engagements if the research is successful. However, given that the particular travel expense in the example occurred prior to commencing the funded research, the link between the pharmaceutical company’s financial interest and the university’s research is less direct than if the research were ongoing when the travel expenses were paid. In sum, the professor in the earlier example likely does not have a financial interest that amounts to a FCOI.

## Conflict Management and Reporting

When an institutional official determines that a FCOI exists, the agency must follow five steps.<sup>59</sup> First, before an Institution expends any funds awarded from the funding agency, the Institution must develop a management plan to address any FCOI.<sup>60</sup> For example, an Institution could disclose the conflict in a footnote to the published research,<sup>61</sup> appoint an independent monitor with the power to modify the research design and report the bias resulting from the conflict,<sup>62</sup> modify the research plan,<sup>63</sup> change or disqualify personnel assigned to the research,<sup>64</sup> reduce the conflicting financial interest itself,<sup>65</sup> or sever the relationship that creates the conflict.<sup>66</sup> An Institution must also evaluate and manage any *new* potential conflicts from Investigators who are added after the research begins or when an existing Investigator receives a significant financial interest that did *not* exist at the time the research began.<sup>67</sup> Compliance with a management plan imposed on an Investigator must continue until completion of the research.<sup>68</sup>

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<sup>56</sup> 42 C.F.R. § 50.603; *see also id.* § 50.604(f).

<sup>57</sup> *See supra* “**Example**” in subsection “Financial Disclosure by Investigators.”

<sup>58</sup> *See* 42 C.F.R. § 50.603.

<sup>59</sup> *See id.* § 50.604(g)–(f).

<sup>60</sup> *See id.* § 50.605.

<sup>61</sup> When human subjects are part of the research, disclosure directly to the individual subjects is also permissible. *See id.* § 50.605(a)(1)(ii).

<sup>62</sup> *Id.* § 50.605(a)(1)(iii).

<sup>63</sup> *Id.* § 50.605(a)(1)(iv).

<sup>64</sup> *Id.* § 50.605(a)(1)(v).

<sup>65</sup> *Id.* § 50.605(a)(1)(vi).

<sup>66</sup> *See id.* § 50.605(a)(1) (vii). Once the research begins, the Institution must conduct the same review for any new participants added to the research within 60 days after beginning participation. *See id.* § 50.605(a)(2).

<sup>67</sup> *See id.* § 50.605(a)(3)(i). In addition, “retrospective review” for potential bias in research is required for any conflict that existed, but for whatever reason was not disclosed at the time the management plan was initially implemented. *Id.* § 50.605(a)(3)(ii).

<sup>68</sup> *See id.* § 50.605(a)(4). In addition, any Institution receiving PHS-funds must also ensure public accessibility to certain FCOI information relating to “senior” or “key” personnel. *See id.* § 50.605(a)(5). Accessibility may be through a publicly available website or through response to a written request within five business days. *See id.* A senior or key personnel is the project director or principal Investigator or any other person identified as a senior or key personnel by the Institution during the grant application process. *See id.* § 50.503. The Institution must permit access to the name and (continued...)



Second, an Institution must comply with ongoing monitoring and reporting requirements.<sup>69</sup> An Institution must submit a report prior to expending any funds for all conflicts that are not entirely eliminated under the Institution’s management plan.<sup>70</sup> Moreover, whenever a conflict is discovered subsequent to the submission of the initial FCOI report, the Institution must update the report within 60 days to note the new conflict and to explain how a management plan has been implemented to prevent the new conflict from influencing the results of the underlying research.<sup>71</sup> Each FCOI report must state the nature and extent of the conflicting interest and must explain why the relationship of the interest to the funded research rises to a conflict.<sup>72</sup> In addition, a FCOI report must describe key elements of an Institution’s management plan, including “[h]ow the management plan is designed to safeguard objectivity in the research project.”<sup>73</sup> An Institution must also submit an annual FCOI report that documents the status of all FCOIs and any changes the Institution has made to the management plan.<sup>74</sup>

Third, an Institution must maintain adequate records of (1) all disclosures by Investigators, (2) the Institution’s response to the disclosures, and (3) all actions taken under the Institution’s FCOI policy for three years from the date the final report on expenditures is submitted to the funding agency.<sup>75</sup>

Fourth, an Institution must establish sufficient “enforcement mechanisms” to ensure employees comply with all required elements of the Institution’s FCOI policy.<sup>76</sup> The PHS regulations suggest that an Institution should be ready to use “employee sanctions or other administrative actions” in order to “ensure Investigator compliance” with FCOI policy.<sup>77</sup>

Fifth, an Institution must certify with the application for funding that the Institution (1) has an up-to-date FCOI policy in writing, (2) will enforce the requirements of the policy against Investigators, (3) will manage discovered FCOIs in compliance with the regulations, and (4) will promptly comply with any disclosure information requested by HHS even if the disclosure was not determined to be a conflict.<sup>78</sup>

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(...continued)

title of the senior personnel, the name of the entity in which the conflicting interest is held, the nature of the interest, and the approximate dollar amount within the permitted ranges. *See id.* § 50.605(a)(5)(ii). Permissible ranges are: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000 and \$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. *See id.*

<sup>69</sup> *See id.* § 50.605(b)(1)–(2). Eliminated conflicts shall not be disclosed to the funding agency. *See id.* § 50.605(b)(1) (“In cases in which the Institution identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, the Institution shall not submit an FCOI report to the PHS Awarding Component.”).

<sup>70</sup> *See id.* § 50.605(b)(1).

<sup>71</sup> *See id.* § 50.605(b)(2). Moreover, whenever a conflict subject to “retrospective review,” *see supra* note 67, and bias has been discovered by the Institution, the Institution is required to notify PHS “promptly and submit a mitigation report....” *See id.* § 50.605(a)(3)(ii).

<sup>72</sup> *See id.* § 50.605(b)(3).

<sup>73</sup> *See id.* § 50.605(b)(3)(viii)(C).

<sup>74</sup> *See id.* § 50.605(b)(4).

<sup>75</sup> *See id.* § 50.604(i).

<sup>76</sup> *See id.* § 50.604(j).

<sup>77</sup> *Id.*

<sup>78</sup> *See id.* § 50.604(k).

All PHS funding agencies are empowered to take corrective actions against an Institution for failure to comply with the regulations.<sup>79</sup> Agency actions may range from a recommendation from the agency for how to resolve the noncompliance to the suspension of funding altogether.<sup>80</sup> As a consequence, through the five aforementioned steps, an Institution can potentially effectively manage and control a FCOI so that the conflict does not invidiously influence the federally supported biomedical research.

Returning to the **Example**<sup>81</sup> regarding travel expenses, even if the travel expenses of the professor were determined to create a FCOI, the professor's university could impose procedures to minimize the potential for actual bias. For example, the university might require the disclosure of the travel expenses in a footnote to the professor's research results. Moreover, the university might prohibit the professor from accepting travel expenses paid by pharmaceutical companies in the future.<sup>82</sup> In order to ensure that the professor complies with the management plan, the university may think of suspending the professor or otherwise sanctioning him if he, for example, continues to accept travel expenses from a pharmaceutical company after the PHS-funded research project begins.<sup>83</sup> Finally, the university in the example will need to comply with PHS FCOI reporting and certification policies with respect to the professor's conflict to ensure the funding agency is aware that the potential conflict is being properly managed.<sup>84</sup>

## HHS Common Rule and FCOIs

Beyond the general objectivity requirements for PHS-funded research, special protections exist for research involving *human* subjects.<sup>85</sup> These regulations, known as the HHS Common Rule, are broad in scope, cover more than just biomedical research, relate to a host of subjects beyond FCOIs, and have been adopted by a host of agencies outside of HHS.<sup>86</sup> Nonetheless, because biomedical research, such as research respecting a new drug or a medical device, frequently necessitates human subject testing, the HHS Common Rule is potentially relevant for managing conflicts of interest, including FCOIs, that may arise during such research.<sup>87</sup> Protection for human

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<sup>79</sup> See *id.* § 50.606(a).

<sup>80</sup> See *id.* § 50.606(b).

<sup>81</sup> See *supra* “**Example**” in subsection “Financial Disclosure by Investigators.”

<sup>82</sup> Even if the interest in the example is not an FCOI, Institutional officials may recognize the potential for harm resulting from an FCOI increases when human subjects are involved and when the research relates to an illness or disease of great significance. See, e.g., Robin Fretwell Wilson, *The Death of Jesse Gelsinger: New Evidence of the Influence of Money and Prestige in Human Research*, 36 AM. J.L. & MED. 295 (2010).

<sup>83</sup> See 42 C.F.R. § 50.604(j).

<sup>84</sup> *Id.* §§ 50.604(i), (k); 50.605(b)(1)–(2).

<sup>85</sup> 45 C.F.R. pt. 46 subpart A. Although beyond the scope of this report, HHS has also promulgated rules that apply to specific subsets of at risk populations, see for example, *See id.* pt. 46 subpart (B)–(D).

<sup>86</sup> The other federal agencies that follow the Common Rule are: Soc. Security Admin., P.L. 103-296, Title I, § 106(b); Dep't of Homeland Security, P.L. 108-458, Title VIII, Subtitle C, § 8306; Dep't of Agriculture, 7 C.F.R. pt. 1c; Dep't of Energy, 10 C.F.R. pt. 745; NASA, 14 C.F.R. pt. 1230; Dep't of Commerce, 15 C.F.R. pt. 27; Consumer Products Safety Comm'n, 16 C.F.R. pt. 1028; Int'l Dev. Cooperation Agency and USAID, 22 C.F.R. pt. 225; Dep't of Housing and Urban Dev., 25 C.F.R. pt. 60; Dep't of Justice, 28 C.F.R. pt. 46; Dep't of Defense, 32 C.F.R. pt. 219; Dep't of Education, 34 C.F.R. pt. 97; Dep't of Vet. Aff., 38 C.F.R. pt. 16; EPA, 40 C.F.R. pt. 26; NSF, 45 C.F.R. pt. 690; Dep't of Transp., 49 C.F.R. pt. 11; Cent. Intelligence Agency, Exec. Order 12,333, pt. 2.10, 46 Fed. Reg. 59,941 (Dec. 8, 1981).

<sup>87</sup> 21 C.F.R. § 312.21; see also *Learn About Clinical Trials*, CLINICALTRIALS.GOV, <http://clinicaltrials.gov/ct2/about-studies/learn#WhatIs> (last reviewed Aug. 2012).



subjects used in medical research is based on the Nuremberg Code which developed in the aftermath of World War II.<sup>88</sup> The congressionally mandated National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research made further contributions to the ethical principles for research involving human subjects.<sup>89</sup> In 1978, the Commission issued the Belmont Report, which established the basic ethical principles that led to the promulgation of the Common Rule by HHS.<sup>90</sup>

The HHS Common Rule applies to all research involving human subjects that is “conducted, supported or otherwise subject to regulation by any federal department or agency...”<sup>91</sup> When research involving human subjects is not directly funded or supported by a federal agency, the Common Rule only applies to “research activities for which a federal department or agency has *specific responsibility* for regulating as a research activity.”<sup>92</sup> An example of when an agency has a “specific responsibility” for regulating a research activity is the FDA’s role in overseeing the development of new human drugs.<sup>93</sup> Importantly, research conducted by a private company is not subject to the HHS Common Rule merely because the company is “incidentally” regulated by an agency because of that agency’s role in regulating certain types of activities that may or may not pertain to research.<sup>94</sup> As a consequence, the HHS Common Rule does not include, for example, the research activities of a private university merely because the Department of Labor enforces generally applicable labor laws that may apply to the university.<sup>95</sup> In addition, the HHS Common Rule specifically exempts certain categories of human subject research.<sup>96</sup> For example, exemptions apply to commonly accepted educational testing practices, research involving publicly available data, public program evaluations, and food quality evaluations.<sup>97</sup>

The primary implementation mechanism for the Common Rule is an Institutional Review Board (IRB).<sup>98</sup> If the research is “conducted or supported by” a federal agency, the reviewing IRB must provide “written assurance” of compliance with the regulations to the agency.<sup>99</sup> If the research is not funded or supported by a federal agency, written assurance is not required, though the research is usually still reviewed by the IRB per the institution’s individual policy.<sup>100</sup> The Common Rule requires that each IRB be comprised of diverse members who are qualified to “ascertain the acceptability of proposed research” based on the applicable laws, institutional policy, and standards of professional conduct.<sup>101</sup> If an IRB member “has a conflicting interest”

<sup>88</sup> 2 Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law no. 10, Nuremberg, October 1946-April 1946, 181-82 (1946), available at [http://www.loc.gov/rr/frd/Military\\_Law/pdf/NT\\_war-criminals\\_Vol-II.pdf](http://www.loc.gov/rr/frd/Military_Law/pdf/NT_war-criminals_Vol-II.pdf).

<sup>89</sup> National Research Act, P.L. 93-348, 88 Stat. 342 (1974).

<sup>90</sup> See *Federal Policy for the Protection of Human Subjects (‘Common Rule’)*, HHS.GOV, <http://www.hhs.gov/ohrp/humansubjects/commonrule/>; 45 C.F.R. Part 46.

<sup>91</sup> 45 C.F.R. § 46.101(a).

<sup>92</sup> See *id.* § 46.102(e).

<sup>93</sup> *Id.*

<sup>94</sup> *Id.*

<sup>95</sup> *Id.*

<sup>96</sup> *Id.* § 46.101(b).

<sup>97</sup> See *id.*

<sup>98</sup> *Id.* § 46.109.

<sup>99</sup> See *id.* § 46.103(a).

<sup>100</sup> See *id.* § 46.101(f).

<sup>101</sup> See *id.* § 46.107(a).

with his obligations to the IRB, he may not participate in the review.<sup>102</sup> The Common Rule does not prescribe any specific disclosure requirements for financial or other interests that have the potential to conflict with an IRB member's obligations.<sup>103</sup> Presumably, any interest that has the potential to bias a member either in favor or against a specific research proposal would arguably disqualify that member from review.<sup>104</sup> Many universities have added further criteria for when an IRB member has a conflict<sup>105</sup> and the procedures for disclosing financial interests.<sup>106</sup>

When the government provides funding for research involving human subjects the IRB's written assurance must be "satisfactory to the department or agency head" that the institution will comply with the minimum safeguards set out by the HHS Common Rule.<sup>107</sup> The assurance must include five elements: (1) a statement of the institution's principles concerning human subject research; (2) a designation of one or more IRBs in accordance with the terms of the regulations; (3) a list of IRB members and biographical information; (4) the written procedures for review that the IRB follows; and (5) the procedures for ongoing monitoring and reporting by researchers at an institution.<sup>108</sup>

The HHS Common Rule defines the responsibilities of IRBs in broad terms, providing IRBs discretion in implementing the rule's mandates.<sup>109</sup> An IRB generally reviews and has the authority to approve, require modification, or disapprove of all research subject to the regulations.<sup>110</sup> Under the Common Rule, an IRB's review of a project primarily focuses on minimizing the risk of harm to the subjects and ensuring the Investigators obtain informed consent from each subject.<sup>111</sup> While the Common Rule does not expressly require an IRB to determine whether individual researchers have FCOIs, an IRB must certify that "[r]isks to subjects are reasonable in relation to anticipated benefits" and "selection of subjects is equitable," potentially implicating how an institution regulates FCOIs and human subject testing.<sup>112</sup> For example, HHS has, in the past, suggested that IRBs should consider "establishing and implementing methods to protect the rights and welfare of human subjects from conflicts of interest created by financial relationships of parties involved

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<sup>102</sup> See *id.* § 46.107(e).

<sup>103</sup> See *id.*

<sup>104</sup> But see Gerald R. Prettyman, Jr., *Ethical Reforms in Biotechnology Research Regulations*, 15 VA. J. SOC. POL'Y & L. 51, 80-81 (Fall 2007) ("The IRB rules do not, however, require anonymous voting, or for the researcher to leave the room after providing the requested information, or prevent the researcher from outside private discussions, or bar others with a conflict of interest from discussing the merits of a research project with an IRB member."); Douglas Andrew Grimm, *Informed Consent for All! No Exceptions*, 37 N.M.L.Rev. 39, 63 (Winter 2007) (arguing that the composition of IRB membership inherently invites conflicts of interest).

<sup>105</sup> See, e.g., Univ. Cal. San Diego, *Human Research Protections Program, Institutional Review Board Standard Operating Policies and Procedures* Sec. 3.8, available at <https://irb.ucsd.edu/3.8.pdf>; Univ. of Ill. at Champaign-Urbana, *Conflicts of Interest—Interim UIUC Policy* (July 2001), available at <http://irb.illinois.edu/?q=ethics/conflicts-of-interest.html>.

<sup>106</sup> Yale Univ. Human Research Protection Program, *Procedures for Disclosing Financial and Non-Financial Interests Related to Research* (Aug. 24, 2012), available at [http://www.yale.edu/hrpp/members/documents/500PR1DisclosureIRBMembersandStaff\\_FINAL.pdf](http://www.yale.edu/hrpp/members/documents/500PR1DisclosureIRBMembersandStaff_FINAL.pdf).

<sup>107</sup> See 45 C.F.R. § 46.103(a).

<sup>108</sup> See *id.* § 46.103(b)(1)–(5).

<sup>109</sup> See *id.* §§ 46.108–111.

<sup>110</sup> See *id.* § 46.109.

<sup>111</sup> See *id.* The general requirements for informed consent are found at *id.* § 46.116.

<sup>112</sup> See *id.* § 46.111(a).

in research.”<sup>113</sup> Accordingly, while no specific financial disclosures are federally mandated, FCOIs appear to be well within the discretionary scope of an IRB’s authority.<sup>114</sup> Nonetheless, notwithstanding such discretion, the National Institutes of Health has estimated that only 25% of IRBs currently routinely deal with FCOIs.<sup>115</sup>

## FDA Rules Regulating FCOIs

Although the FDA is within the purview of PHS, the FDA’s unique role as “gatekeeper” for the approval of certain products entering the open market has resulted in a different approach with respect to FCOIs.<sup>116</sup> First, the FDA has its own rules governing human subject research and IRBs.<sup>117</sup> The FDA’s version of the Common Rule most notably differs from the HHS Common Rule in scope. Specifically, the FDA Common Rule applies to (1) “all clinical investigations” pertaining to investigational drugs<sup>118</sup> and investigational devices<sup>119</sup> and (2) “clinical investigations that support applications for research or marketing” for several products regulated by the FDA, including foods, drugs for human use, medical devices for human use, and biological products for human use.<sup>120</sup> In other words, in contrast to the HHS Common Rule, even clinical trials for new drugs and devices that are wholly *privately* funded are potentially subject to the FDA Common Rule.<sup>121</sup>

While the FDA’s version of the Common Rule covers both federally supported and privately funded clinical research, the HHS Common Rule and the FDA’s counterpart largely mirror each other.<sup>122</sup> And the similarities between the two rules extend to their treatment of FCOIs. In particular, like the HHS Common Rule, the FDA regulations on human subject testing bar a member of IRB from participating in the review of a project if that member has a “conflicting interest.”<sup>123</sup> Moreover, as with the HHS Common Rule, the FDA’s counterpart does not overtly

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<sup>113</sup> *Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection*, 69 Fed. Reg. 26,393, 26,396-97 (May 12, 2004) (proposing legally nonbinding mechanisms by which IRBs can identify and mitigate FCOIs that may affect the rights of human subjects and third parties).

<sup>114</sup> See, e.g., Univ. Cal. San Diego, *supra* note 105; and Yale Univ. Human Research Protection Program, *supra* note 106.

<sup>115</sup> See NIH Guidance, *Financial Conflicts of Interest and Research Objectivity: Issues for Investigators and Institutional Review Boards* (June 5, 2000), available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-040.html>.

<sup>116</sup> See James T. O’Reilly, *Losing Deference in the FDA’s Second Century: Judicial Review, Politics, and a Diminished Legacy of Expertise*, 93 CORNELL L. REV. 939, 949 (2008).

<sup>117</sup> See *id.* pt. 50 and pt 56.

<sup>118</sup> See 21 U.S.C. § 355(i); see also 21 C.F.R. pt.

<sup>119</sup> See 21 U.S.C. § 360j(g); see also 21 C.F.R. pt. 812.

<sup>120</sup> 21 C.F.R. §§ 50.1(a) & 56.101(a). The listed products subject to the FDA Common Rule are: “foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, biological products for human use, and electronic products.” See *id.* § 50.1(a); see also *id.* § 56.101(a).

<sup>121</sup> See *id.* § 56.103(a). The rationale for the difference from the HHS Common Rule is that the FDA’s jurisdiction generally extends to clinical trials for any drugs or devices intended for human use that may enter interstate commerce. 21 U.S.C. § 355; see *id.* § 360j.

<sup>122</sup> See generally 21 C.F.R. § 56.107. For a comparison of the two rules, see Bonnie M. Lee, U.S. FOOD AND DRUG ADMIN., *Comparison of FDA and HHS Human Subject Protection Regulations* (March 2009), <http://www.fda.gov/scienceresearch/specialtopics/runningclinicaltrials/educationalmaterials/ucm112910.htm>.

<sup>123</sup> 21 C.F.R. § 56.107(e).

govern FCOIs that a researcher or institution may have and instead defers to an institution's IRB to monitor potential conflicts.<sup>124</sup>

In 1991, the Inspector General of HHS, sensing a need for the FDA to move beyond the FDA Common Rule's concepts regarding financial conflicts, issued a report directed at the FDA that noted the failure of the agency to have a mechanism for collecting information on FCOIs of clinical investigators who study products that undergo FDA review.<sup>125</sup> The Inspector General's report led the FDA to conclude that there was a "need to address" through regulations the issue of FCOIs with respect to the clinical tests performed on FDA-covered products.<sup>126</sup> In 1998, the FDA promulgated several specific regulations requiring the submission of certain financial information with respect to marketing applications that rely on clinical data.<sup>127</sup> The current FDA disclosure requirements apply to all "marketing applications" for all human drugs, biological products, and devices.<sup>128</sup>

The FDA FCOI regulations generally give less deference to the institution performing the research than the PHS objectivity requirements.<sup>129</sup> In particular, under the FDA's policy, the institution generally does not conduct the primary review of FCOIs by the clinical investigators. Instead, any applicant who submits a covered marketing application is "responsible" for submitting certain financial interest information to the FDA for review.<sup>130</sup> The FDA then must determine "the impact of any disclosed financial interest on the reliability of the study."<sup>131</sup> The FDA may deem a clinical study that is the basis for market approval inadequate if steps have not been taken to minimize bias, including "a financial interest of the clinical investigator in the outcome of the study."<sup>132</sup>

Pursuant to the FDA's FCOI rules, the applicant must first submit a list of all investigators employed by the sponsor of the study.<sup>133</sup> For each investigator, the applicant must either (a) certify that no "financial arrangements" exist or (b) disclose the nature of those financial arrangements that do exist.<sup>134</sup> A financial arrangement can be any of the following:

1. Compensation affected by the outcome of the clinical studies—that is, compensation that is higher if the product or device is approved by the FDA.<sup>135</sup>
2. A significant equity interest in the sponsor.<sup>136</sup> If the sponsor is a non-public entity, then any interest for which the value cannot be readily established is

<sup>124</sup> See generally *id.* § 56.111 (detailing the criteria for IRB approval of research).

<sup>125</sup> See Office of the Inspector General (OIG), Department of Health and Human Services (DHHS), Management Advisory Report – Financial Involvement of Clinical Investigators with Sponsors of Research Leading to Food and Drug Administration Marketing Approval, June 1991, OI-HQ-91-003.

<sup>126</sup> *Financial Disclosure by Clinical Investigators*, 63 Fed. Reg. 5,233, 5,235 (Feb. 2, 1998).

<sup>127</sup> *Id.* (to be codified at 21 C.F.R. pt. 54).

<sup>128</sup> See 21 C.F.R. § 54.3.

<sup>129</sup> See *id.* § 54.5.

<sup>130</sup> See *id.* § 54.3.

<sup>131</sup> See *id.* § 54.5(a).

<sup>132</sup> See *id.*

<sup>133</sup> See *id.*

<sup>134</sup> See *id.*

<sup>135</sup> *Id.* § 54.2(a).

<sup>136</sup> See *id.* § 54.2(b).

- significant.<sup>137</sup> If the sponsor is a public entity, then an interest that exceeds \$50,000 is significant.<sup>138</sup>
3. A proprietary interest in the product such as a patent, trademark, copyright, licensing agreement.<sup>139</sup>
  4. Any other payment from the sponsor to the Investigator of more than \$25,000 that is not for the funding of the clinical trial.<sup>140</sup>

The FDA undertakes a three-part evaluation of all significant financial interests that are disclosed.<sup>141</sup> First, the agency assesses the impact on the reliability of the results of the clinical trial based on the size and nature of the disclosed financial arrangement.<sup>142</sup> Second, the agency determines the effect of the financial interests on the study design.<sup>143</sup> Finally, if any “serious questions about the integrity of the data” are raised, the FDA must take appropriate action to ensure the reliability of the clinical trials.<sup>144</sup> The FDA is authorized to (1) audit the investigator; (2) request further analysis by the applicant; (3) request other independent studies; or (4) discredit the results of the study.<sup>145</sup>

## Other Agency Requirements With Respect to FCOIs

### National Science Foundation FCOI Policy

When compared to the PHS objectivity requirements, the National Science Foundation (NSF) has a similar, but arguably less strict, FCOI policy for funded research.<sup>146</sup> Pursuant to NSF’s policy, all “grantee institutions” with more than 50 employees must maintain a “written and enforced” FCOI policy.<sup>147</sup> NSF requires that all investigators<sup>148</sup> must disclose (1) any “significant financial interest” to the responsible party with the institution if the significant interest “reasonably appear[s] to be affected by” the research, or (2) if the research could reasonably appear to affect the financial interests of the entity in which the Investigator holds a significant interest.<sup>149</sup> NSF further defines a significant interest as anything<sup>150</sup> with a monetary value over \$10,000.<sup>151</sup>

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<sup>137</sup> *See id.*

<sup>138</sup> *See id.*

<sup>139</sup> *See id.* § 54.2(d)

<sup>140</sup> *See id.* § 54.2(f).

<sup>141</sup> *See id.* § 54.5.

<sup>142</sup> *See id.* § 54.5(a).

<sup>143</sup> *See id.* § 54.5(b).

<sup>144</sup> *See id.* § 54.5(c).

<sup>145</sup> *Id.*

<sup>146</sup> NATIONAL SCIENCE FOUNDATION, GRANTEE POLICY MANUAL § 510, available at [http://www.nsf.gov/pubs/manuals/gpm05\\_131/gpm5.jsp#510](http://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp#510).

<sup>147</sup> *See id.*

<sup>148</sup> The term “Investigator” mirrors the PHS definition and includes: the principal investigator, co-principal investigators, and any other person at the institution who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by NSF. *Id.*

<sup>149</sup> *See id.*

<sup>150</sup> The NSF definition includes salaries, payment for services, equity interests, and intellectual property rights. *Id.*

However, the NSF policy excludes the following from the definition of a significant financial interest:

1. Remuneration from the grantee institution to the Investigator;
2. An ownership interest in the institution if the institution is a Small Business Innovation Research Program or Small Business Technology Transfer Program;
3. Income from teaching or speaking engagements paid by public or non-profit organizations;
4. Income from serving on advisory panels for public or non-profit organizations;
5. Aggregated interests, including the interests of a spouse or dependents, that do not exceed \$10,000 or a 5% ownership share; and
6. Aggregated interests, including the interests of a spouse or dependents, that do not exceed \$10,000 in a 12-month period.<sup>152</sup>

The NSF standard for when a significant financial interest becomes a conflict is the same as the PHS standard<sup>153</sup>—that is, when “a significant financial interest could directly and significantly affect the design, conduct, or reporting of NSF-funded research or educational activities.”<sup>154</sup> A designated representative of the institution is responsible for determining whether any of the disclosed significant financial interests rise to the level of a FCOI.<sup>155</sup> If a conflict is found, NSF requires that the institution must impose “conditions or restrictions” to manage the conflict and prevent judgment bias.<sup>156</sup> In contrast to the PHS FCOI policy, however, under the NSF financial conflict rules the reviewer may balance the benefit of the research against the potential negative impact of the conflict and decide not to impose restrictions if those restrictions would be ineffective or inequitable.<sup>157</sup> Moreover, while PHS policy requires the government to be continually informed as to how a potential conflict has been managed or eliminated,<sup>158</sup> under the NSF rules, an institution need only report FCOIs that have not been “satisfactorily” managed.<sup>159</sup> Collectively, the NSF’s waiver and reporting provisions make the NSF requirements arguably less stringent than the PHS-agency requirements.<sup>160</sup>

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(...continued)

<sup>151</sup> *See id.* The definition includes interests of a spouse or dependent. *See id.* Compare with the PHS threshold of \$5,000. 42 C.F.R. § 50.603.

<sup>152</sup> *See id.*

<sup>153</sup> *See* 42 C.F.R. § 50.604(f) (defining a FCOI as a “significant financial interest [that] could directly and significantly affect the design, conduct or reporting of the PHS-funded research.”).

<sup>154</sup> NATIONAL SCIENCE FOUNDATION, GRANTEE POLICY MANUAL § 510(d).

<sup>155</sup> *See* § 510(a).

<sup>156</sup> *See id.* § 510(d).

<sup>157</sup> *See id.*

<sup>158</sup> *See* 42 C.F.R. § 50.605(b)(4).

<sup>159</sup> NATIONAL SCIENCE FOUNDATION, GRANTEE POLICY MANUAL § 510(f).

<sup>160</sup> Mark Barnes and Patrik S. Florencio, *Investigator, IRB, and Institutional Conflicts of Interest in Human-Subjects Research: Past, Present and Future*, 32 SETON HALL L. REV. 525, 536 (2002) (arguing that the “NSF policy allows an institution more discretion than that allowed by PHS in its obligation to manage” FCOIs).



## Department of Defense FCOI Policy

The Department of Defense (DOD) provides funding opportunities for biomedical research through the Congressionally Directed Medical Research Programs (CDMRP).<sup>161</sup> Current opportunities for DOD funding include, for example, grants for research in bone marrow failure,<sup>162</sup> behavioral trials for autism patients,<sup>163</sup> and research to improve the lives of veterans suffering from Gulf War Illness.<sup>164</sup> According to DOD FCOI policy, the names of all “scientific participants” and “those individuals outside the application” who might have a conflict of interest must be disclosed by the applicant during the electronic “pre-application submission” process.<sup>165</sup> While the DOD’s funding application instructions provide no further guidance about the criteria for evaluating potential conflicts, the instructions refer all applicants back to their institution’s policy concerning the disclosure of potential conflicts.<sup>166</sup> In most cases, the institution’s policy is not limited to PHS-funded research but extends to all research conducted by the research institution’s employees.<sup>167</sup> Therefore, as a practical matter, applicants for biomedical research funding from the DOD may need to comply with stricter requirements than the PHS regulations. Furthermore, the DOD has adopted the HHS Common Rule for applicable human subject research.<sup>168</sup>

## Current Developments

In 2011, the PHS “objectivity in research” regulations for the disclosure of FCOIs were revised to their current form.<sup>169</sup> The revisions to the PHS objectivity rules included the lowering of financial interest reporting thresholds, expanding reporting obligations, and requiring institutions receiving

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<sup>161</sup> DEP’T OF DEFENSE, *Congressionally Directed Medical Research Programs*, <http://cdmrp.army.mil/default.shtml> (last updated July 17, 2014).

<sup>162</sup> DEP’T OF DEFENSE, W81XWH-14-BMFRP-IDA, *Congressionally Directed Med. Res. Programs, Bone Marrow Failure Res., Program Idea Development Award (2014)*, available at [http://cdmrp.army.mil/funding/pa/14bmfrpida\\_pa.pdf](http://cdmrp.army.mil/funding/pa/14bmfrpida_pa.pdf).

<sup>163</sup> DEP’T OF DEFENSE, W81XWH-14-ARP-CTA, *Congressionally Directed Med. Res. Programs, Autism Res. Program, Clinical Trial Award (2014)*, available at [http://cdmrp.army.mil/funding/pa/14arpcta\\_pa.pdf](http://cdmrp.army.mil/funding/pa/14arpcta_pa.pdf).

<sup>164</sup> DEP’T OF DEFENSE, W81XWH-14-GWIRP-NIA, *Congressionally Directed Med. Res. Programs, Gulf War Illness Res. Program, New Investigator Award (2014)*, available at [http://cdmrp.army.mil/funding/pa/14gwirpnia\\_pa.pdf](http://cdmrp.army.mil/funding/pa/14gwirpnia_pa.pdf).

<sup>165</sup> *General Application Instructions, Fiscal Year 2013, Defense Health Program*, DEPT. OF DEFENSE, available at [https://cdmrp.org/files/forms/generic/cdmrp\\_instruct.pdf](https://cdmrp.org/files/forms/generic/cdmrp_instruct.pdf).

<sup>166</sup> *Id.*

<sup>167</sup> For example, the University of Virginia’s policy includes research beyond that which is funded by a PHS agency:

The term includes but is not limited to any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act ... or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

See Univ. of Va., *supra* note 16.

<sup>168</sup> See 32 C.F.R. pt. 219. The U.S. Army Medical Dept. Medical Research and Material Command (USAMRMC) Office of Research Protections (ORP) has also adopted guidelines for research involving human subjects, human anatomical substances or animals. *Office of Research Protections*, USAMRMC, [https://mrmc.amedd.army.mil/index.cfm?pageid=research\\_protections.overview](https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.overview) (last modified Sept. 14, 2012).

<sup>169</sup> *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors*, 76 Fed. Reg. 53,256 (Aug. 25, 2011).

federal funds to develop and enforce policies on FCOIs through training and education programs.<sup>170</sup> Although the revisions arguably increased clarity and transparency with respect to the PHS financial conflict rules,<sup>171</sup> the administration of the PHS FCOI process is still largely left to grantee institutions.<sup>172</sup> As a result, even though a relatively small number of federal laws govern FCOI with respect to biomedical research, the process is still potentially cumbersome for investigators who participate in research with multiple institutions because each institution may have different processes for complying with the same federal rules.<sup>173</sup>

Beyond potential issues arising because of a lack of uniformity among biomedical research institutions, the delegation of FCOI oversight to individual institutions arguably risks compliance problems, with some institutions inevitably having more lax financial conflict policies than others.<sup>174</sup> Some commentators have even suggested that the discrepancies among research institutions with respect to their FCOI policies may lead to a “race to the bottom” where investigators “leave institutions with stringent policies to go to more lenient ones.”<sup>175</sup> Others have raised concerns that the delegation of the administration of FCOI policies to grantee institutions generally has resulted in FCOI policies that are vague and provide little guidance to researchers as to the “kinds of relationships with industry that are permitted or prohibited.”<sup>176</sup> As a consequence, some have advocated for a uniform federal conflict of interest policy that must be followed by all institutions and investigators applying for federal funds.<sup>177</sup> At the same time, others have cautioned against imposing a “one size fits all” conflict management approach because “a degree of flexibility is essential to maintaining a balance between ‘caution’ and ‘an environment in which legitimate research can flourish.’”<sup>178</sup> Regardless, as a consequence of the

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<sup>170</sup> *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors*, 76 Fed. Reg. 53,256, 53,257-58 (Aug. 25, 2011).

<sup>171</sup> See Rockey and Collins, *supra* note 4, at 2400-01 (examining proposed regulations that were eventually promulgated as a final rule).

<sup>172</sup> See AAMC REPORT *supra* note 41, at 1.

<sup>173</sup> See *id.* at 2.

<sup>174</sup> See Jesse A. Goldner, *Regulating Conflicts of Interest in Research: The Paper Tiger Needs Real Teeth*, 53 ST. LOUIS L.J. 1211, 1245-46 (Summer 2009); see also Elizabeth A. Boyd et al., *Implementation of Financial Disclosure Policies to Manage Conflicts of Interest*, 23 HEALTH AFF. 206, 213 (2004) (“In the absence of a clear and consistent definition of conflict of interest, individual committees have developed their own sets of standards in evaluating financial disclosures. Those standards appear to be based on specific institutional values that the committees felt were important to protect.”).

<sup>175</sup> See Marcia Angell, *Address at the NIH Conference on Human Subject Protection and Financial Conflicts of Interest* (Aug. 16, 2000), <http://archive.hhs.gov/ohrp/coi/8-16.htm#Angell>.

<sup>176</sup> Mildred K. Cho et al., *Policies on Faculty Conflicts of Interest at US Universities*, 284 JAMA 2203, 2208 (2000) (“Most policies on conflict of interest at major US research institutions lack specificity about the kinds of relationships with industry that are permitted or prohibited.”).

<sup>177</sup> See Mhairi Ransom, *Drugs and Money, The Impact of Industry “Donated” Money on Public Research and the Need for Stricter Conflict of Interest Standards*, 17 S. Cal. Interdis. L.J. 567, 585 (Spring 2008) (“By having a uniform policy that is followed by all Institutions and Investigators applying for federal funds, the federal government will make it easier for funding agencies to analyze compliance, as they will be familiar with the policy’s requirements and procedures.”).

<sup>178</sup> See Bernadette M. Broccolo and Jennifer S. Geetter, *Today’s Conflict of Interest Compliance Challenge: How Do We Balance the Commitment to Integrity with the Demand for Innovation*, Vol. 1, No. 4 J. HEALTH AND LIFE SCI. L. 1; see also Robert Gatter, *Human Subject Research and Conflicts of Interest: Walking the Talk of Trust in Human Subjects Research: The Challenge of Regulating Financial Conflicts of Interest*, 52 EMORY L.J. 327, 352-53 n.123 (Winter 2003) (“[A] chief reason for the law to continue to rely on researchers and research institutions to police their own financial conflicts of interest is the public policy goal of promoting trustworthiness in the human research enterprise. To effectively promote trustworthy behavior by researchers and research institutions’ respect of conflicts of (continued...)”).



most recent revisions to the PHS objectivity rules, the debate over the appropriate scope and reach of federal FCOI regulations with respect to biomedical research, which has at times “captured the attention” of Congress,<sup>179</sup> will likely continue.

While the PHS general objectivity requirements have been recently updated, the HHS and FDA rules respecting human subject research have not been substantially altered in decades.<sup>180</sup> As a consequence, the HHS and FDA have jointly provided advance notice of proposed rulemaking (ANPR) to “modernize” the Common Rule.<sup>181</sup> With respect to FCOIs, the ANPR noted that a key “problem[]” with the current version of the Common Rule is its failure to ensure that institutions effectively provide human test subjects with “appropriate information about [the] financial relationships between researchers and study sponsors....”<sup>182</sup> To remedy this problem, HHS has requested comments about whether the Common Rule should be amended to require that institutions disclose in consent forms “information about financial relationships [researchers] have with [their] sponsors.”<sup>183</sup> More broadly, the ANPR has suggested that (1) the scope of the HHS Common Rule should be expanded to reach all research activities at domestic institutions that receive “some funding from a Common Rule agency”<sup>184</sup> and (2) the federal rules on human subject testing should be harmonized and refined across adopting agencies.<sup>185</sup> While a new Common Rule that is broader in scope and more precise and uniform could potentially expand the rule’s impact on FCOI management with respect to biomedical research, since soliciting comments from the public in July of 2011, HHS has not yet issued any new final rules amending the Common Rule.<sup>186</sup> In addition to the Common Rule ANPR, in July 2014 the FDA announced new *draft* guidance on human subject testing and sought public commentary on the guidance.<sup>187</sup> Included in the draft guidance was a series of broad recommendations that “clinical investigators should consider whether information related to financial relationships or interests should be

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(...continued)

interest, the law must signal its willingness to trust researchers and research institutions to do just that.”).

<sup>179</sup> See Jennifer J. Kulynych, *The Regulation of MR Neuroimaging Research: Disentangling the Gordian Knot*, 33 AM. J. L. AND MED. 295, 316 (2007) (noting that the concept of a “a single federal office promulgating one set of regulations for all research” has “captured the attention of Congress and the Executive branch.”) (citing Research Revitalization Act of 2002, S. 3060, 107<sup>th</sup> Cong. (2002); Human Research Subject Protection Act of 2002, H.R. 4697, 107<sup>th</sup> Cong. (2002)).

<sup>180</sup> See Federal Policy for the Protection of Human Subjects, 56 Fed. Reg. 28,003 (June 18, 1991) (amending the HHS Common Rule); see also Additional Safeguards for Children in Clinical Investigations of FDA-Regulated Products, 66 Fed. Reg. 20,589 (April 24, 2001) (amending the FDA human subject testing regulations).

<sup>181</sup> *Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators*, 76 Fed. Reg. 44,512 (Jul. 26, 2011) (to be codified at 45 C.F.R. pts. 46, 160, 164 and 21 C.F.R. pts. 50, 56) [hereinafter ANPR].

<sup>182</sup> See 76 Fed. Reg. at 44,513.

<sup>183</sup> See *id.* at 44,523.

<sup>184</sup> *Id.* at 44,528 (“We are considering ... requiring domestic institutions that receive some Federal funding from a Common Rule agency for research with human subjects to extend the Common Rule protections to all research studies conducted at their institution.”).

<sup>185</sup> See *id.* at 44,514 (noting that “the multiple, differing regulatory requirements that can apply to a single research study have been criticized as complex, inconsistent, and lacking in clarity, which results in unwarranted variability across institutions and their IRBs in how the requirements are interpreted and implemented.”).

<sup>186</sup> See *Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators*, Docket # HHS-OPHS-2011-0005, <http://www.regulations.gov/#!docketDetail;D=HHS-OPHS-2011-0005>.

<sup>187</sup> See *Informed Consent Information Sheet: Guidance for IRBs, Clinical Investigators, and Sponsors*, FOOD AND DRUG ADMIN. (July 14, 2014), <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf>.

provided to subjects.”<sup>188</sup> In addition, Members of Congress have at times sought to encourage, through proposed legislation, HHS to expand the Common Rule to explicitly impose regulations respecting the definition and management of potential FCOIs with regard to human subject testing.<sup>189</sup> To date, however, no recent changes to either the HHS or FDA Common Rules have been enacted into law that implicate FCOI policy.

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<sup>188</sup> *Id.* at \*26 (suggesting that investigators should disclose the source of funding and funding arrangements to test subjects).

<sup>189</sup> *See, e.g.*, Research Participants Protection Modernization Act of 2011, H.R. 2625, 112<sup>th</sup> Cong., § 491A (c)(2)(ii) (2011) (proposing that the Secretary of HHS should consider “[h]ow requirements regarding the definition and management of potential financial conflict of interest, including both investigator and institutional conflicts of interest, should be strengthened and enforced to protect human subjects more effectively” and “make a determination of whether any of the provisions of” the Common Rule or “any guidance associated with” it should “should be modified accordingly.”)

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