

1-2021

## Regulatory Challenges for Treating Failure to Disclose FCOI as Research Misconduct in Public Health Research

Tammy M. Frisby

Follow this and additional works at: <https://dc.law.utah.edu/ulr>

---

### Recommended Citation

Frisby, Tammy M. (2021) "Regulatory Challenges for Treating Failure to Disclose FCOI as Research Misconduct in Public Health Research," *Utah Law Review*: Vol. 2020 : No. 5 , Article 5.  
Available at: <https://dc.law.utah.edu/ulr/vol2020/iss5/5>

This Note is brought to you for free and open access by Utah Law Digital Commons. It has been accepted for inclusion in Utah Law Review by an authorized editor of Utah Law Digital Commons. For more information, please contact [valeri.craigle@law.utah.edu](mailto:valeri.craigle@law.utah.edu).

# REGULATORY CHALLENGES FOR TREATING FAILURE TO DISCLOSE FCOI AS RESEARCH MISCONDUCT IN PUBLIC HEALTH RESEARCH

Tammy M. Frisby\*

## I. INTRODUCTION

In the fall of 2018, *The New York Times* reported that world-renowned cancer researcher José Baselga, Chief Medical Officer of Memorial Sloan Kettering Cancer Center in New York, had repeatedly failed to disclose in publications and presentations his significant personal financial ties to pharmaceutical companies as required by both the American Association for Cancer Research and the editorial policies of academic journals.<sup>1</sup> Following on the reporting about Baselga, physician and medical ethicist Jeffrey Botkin argues in an opinion piece in the *Journal of the American Medical Association* that “[i]t is time to strengthen institutional [financial conflict of interest] policies by considering the intentional or negligent failure to disclose significant financial relationships relevant to the conduct of research to be research misconduct.”<sup>2</sup> Botkin argues that compliance with institutional financial conflict of interest (FCOI) disclosure requirements may be improved by creating an incentive for scientific investigators to avoid the damage to professional reputation associated with a finding of “research misconduct.”<sup>3</sup> In addition to his normative contention that “serious noncompliance” with institutional FCOI disclosure requirements should be treated as research misconduct, Botkin suggests that existing federal regulations may provide legal authority for Public Health Service (PHS)

---

\* © 2020 Tammy M. Frisby. Tammy M. Frisby is a third-year law student at the S.J. Quinney College of Law at the University of Utah. Before making a career transition to law, Tammy was a Research Fellow at the Hoover Institution at Stanford University, where she also taught in the university’s political science department and public policy program. She earned her Ph.D. in political science from the Harvard University GSAS Department of Government. Tammy would like to thank Leslie P. Francis, Jorge L. Contreras, Teneille Brown, and the rest of the SJQ Center for Law and Biomedical Sciences faculty for building an intellectually stimulating and supportive community.

<sup>1</sup> Charles Ornstein & Katie Thomas, *Top Cancer Researcher Fails to Disclose Corporate Financial Ties in Major Research Journals*, N.Y. TIMES (Sept. 8, 2018), <https://www.nytimes.com/2018/09/08/health/jose-baselga-cancer-memorial-sloan-kettering.html> [<https://perma.cc/472G-BDQT>]. See generally Jorge L. Contreras & Marc Daniel Rinehart, *Conflicts of Interest and Academic Research*, in RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER (Jacob H. Rooksby ed., 2020) (providing an overview of research on the effects of conflicts of interest on academic research as well as a survey of governmental, institutional, and academic journal conflict of interest policies).

<sup>2</sup> Jeffrey R. Botkin, Viewpoint, *Should Failure to Disclose Significant Financial Conflicts of Interest Be Considered Research Misconduct?*, 320 JAMA 2307, 2307 (2018).

<sup>3</sup> *Id.* at 2308.

agencies, including the National Institutes of Health (NIH), to address a PHS-funded researcher's "serious noncompliance" with institutional FCOI disclosure requirements as research misconduct.<sup>4</sup>

This Note assesses the viability of treating failure to disclose FCOI as research misconduct under current law. I find that existing federal regulations likely do not provide legal authority for NIH or other PHS funding-agencies to address failure to disclose FCOI as research misconduct. After providing an overview of current PHS regulations on FCOI and research misconduct, the Note considers four features of administrative law governing bias and integrity in PHS-funded research: (a) the definition of "research misconduct" under current regulations; (b) the regulatory standards for a finding of "research misconduct"; (c) the intent behind the 2004–2005 rulemaking process that revised research misconduct policies across federal agencies; and (d) the regulatory structure within Title 42 of the C.F.R. that was created by the 2004–2005 rulemaking process. Based on existing PHS regulations and the purpose behind the federal policy that guided the 2004–2005 rulemaking on research misconduct, it seems unlikely that current law supports treating even the most serious cases of failure to disclose FCOI *in itself* as research misconduct in violation of PHS regulations. This Note presents alternative recommendations for action by research institutions and PHS funding-agencies to address "serious noncompliance" with FCOI disclosure.

## II. BACKGROUND

PHS research falls under the purview of the Department of Health and Human Services (HHS) and its eight public health service agencies, including NIH.<sup>5</sup> In fiscal year 2018, NIH awarded \$27.1 million in grants and contracts to support medical

---

<sup>4</sup> *Id.* ("To [Botkin's] knowledge, the [Department of Health and Human Services Office of Research Integrity] has not explicitly addressed whether noncompliance with [F]COI regulations or policy could constitute research misconduct[,] but Botkin interprets federal regulatory guidance as supportive of addressing FCOI disclosure noncompliance under federal research misconduct policy).

<sup>5</sup> The eight designated PHS agencies within HHS are: Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), and Substance Abuse and Mental Health Services Administration (SAMHSA). *HHS Agencies & Offices*, HHS, <https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html> [<https://perma.cc/66ZG-YQKC>] (last visited July 30, 2020).

research.<sup>6</sup> Under current law, FCOI disclosure and research misconduct in PHS-funded research are regulated by 42 C.F.R. Parts 50 and 93, respectively.<sup>7</sup>

The PHS regulations governing FCOI disclosure for PHS-funded research are codified at 42 C.F.R. §§ 50.601–607.<sup>8</sup> Under PHS regulations, a “financial conflict of interest” is defined as “a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.”<sup>9</sup> At 42 C.F.R. §§ 50.604–605, the rules assign research institutions the responsibility to establish institutional FCOI disclosure requirements and management plans for PHS-funded researchers, as well as procedures for reporting FCOI to the PHS-funding agency, consistent with 42 C.F.R. §§ 50.601–607.<sup>10</sup> When an institution discovers that an FCOI was not disclosed by an “investigator,”<sup>11</sup> the institution must conduct “a retrospective review of the [i]nvestigator’s activities and the PHS-funded research project to determine whether any PHS-funded research . . . conducted during the time period of noncompliance, was biased in the design, conduct, or reporting of such research.”<sup>12</sup> Although a PHS funding-agency, under 42 C.F.R. § 50.606(b), may decide to take additional corrective action by imposing specific award conditions under 45 C.F.R. § 75.207, or suspending funding or taking other enforcement action under 45 C.F.R. § 75.371, the research institution is primarily responsible for taking corrective action in response to a PHS-funded researcher’s failure to disclose FCOI, based on its institutional policies.<sup>13</sup>

---

<sup>6</sup> Table #106 NIH Research Grants and Other Mechanisms Including Research and Development Contracts, NIH, <https://report.nih.gov/DisplayRePORT.aspx?rid=569> [<https://perma.cc/RTF8-VX79>] (last visited June 7, 2020) (fiscal year 2018 total contained in spreadsheet cell located at row 277, column C).

<sup>7</sup> 42 C.F.R. §§ 50.601–607 (2019) (FCOI disclosure rules are contained in part 50, subpart F titled “Promoting Objectivity in Research”); *id.* §§ 93.100–523 (part 93 titled “Public Health Service Policies on Research Misconduct”).

<sup>8</sup> *Id.* §§ 50.601–607.

<sup>9</sup> *Id.* § 50.603 (providing a definition of “significant financial interest”; under current regulations, the threshold for a “significant” interest is set at \$5,000 and applies to financial interests held by the investigator, as well as the investigator’s spouse and dependent children, which “reasonably appears to be related to the [i]nvestigator’s institutional responsibilities”).

<sup>10</sup> *Id.* § 50.604 (subsection heading: “Responsibilities of Institutions regarding Investigator financial conflicts of interest”); *id.* § 50.605 (subsection heading: “Management and reporting of financial conflicts of interest”); *id.* §§ 50.601–607 (FCOI rules).

<sup>11</sup> *Id.* § 50.603 (defining “Investigator” as used in the subpart 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”).

<sup>12</sup> *Id.* § 50.605(a)(3)(ii)(A).

<sup>13</sup> *Id.* § 50.606(b); 45 C.F.R. §§ 75.207, 75.371 (2019); 42 C.F.R. § 50.605 (2019); *see also id.* § 50.606(c) (establishing federal requirement for PHS-funded institutions to rectify FCOI nondisclosure related to PHS-funded clinical research whose purpose is to evaluate the safety or effectiveness of medical drugs, devices, or treatment that “[have] been designed, conducted, or reported by an [i]nvestigator with a financial conflict of interest that was not

Research misconduct is regulated by 42 C.F.R. §§ 93.100–523.<sup>14</sup> Under PHS regulations, “[r]esearch misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.”<sup>15</sup> A finding of research misconduct requires: “(a) There be a significant departure from accepted practices of the relevant research community; and (b) The misconduct be committed intentionally, knowingly, or recklessly; and (c) The allegations be proven by a preponderance of the evidence.”<sup>16</sup>

Following a similar structure to FCOI regulations in 42 C.F.R. §§ 50.604–605, research institutions are responsible for identifying and addressing research misconduct by their PHS-funded investigators consistent with 42 C.F.R. Part 93.<sup>17</sup> Unlike FCOI regulations, however, the research misconduct rules in 42 C.F.R. Part 93 establish a procedure to which institutions must adhere when addressing allegations of research misconduct.<sup>18</sup> Upon receipt of an allegation of research misconduct, institutions must notify HHS and convene an inquiry committee tasked with determining whether there is sufficient evidence to warrant a full investigation by a separate investigative committee at the institution.<sup>19</sup>

In contrast to the handling of FCOI, 42 C.F.R. §§ 93.400–414 grants HHS, through the independent Office of Research Integrity (ORI), extensive authority to review and take corrective action following a finding of research misconduct.<sup>20</sup> In addition to assisting and advising institutions conducting their own research misconduct proceedings, ORI “may respond directly to any allegation of research misconduct at any time before, during, or after an institution’s response to the matter.”<sup>21</sup> ORI may make its own finding of research misconduct and propose administrative action to HHS.<sup>22</sup> Unlike the FCOI regulations in 42 C.F.R. Part 50, which have limited reference to HHS-imposed sanctions and refer to another Title of the C.F.R. for possible sanctions,<sup>23</sup> 42 C.F.R. Part 93 includes specific HHS administrative actions to be taken by HHS in response to research misconduct.<sup>24</sup> HHS administrative actions in response to a finding of research misconduct range from special review of all future requests for PHS funding to suspension or

---

managed or reported by the [i]nstitution as required by this subpart; the [i]nstitution shall require the [i]nvestigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations”).

<sup>14</sup> 42 C.F.R. §§ 93.100–523 (2019).

<sup>15</sup> *Id.* § 93.103 (definition of research misconduct).

<sup>16</sup> *Id.* § 93.104 (standards for a finding of research misconduct).

<sup>17</sup> *Id.* §§ 50.604–605; *id.* §§ 93.300–306.

<sup>18</sup> *Id.* §§ 93.307–316.

<sup>19</sup> *Id.* §§ 93.307, 93.310.

<sup>20</sup> *Id.* §§ 93.400–414.

<sup>21</sup> *Id.* § 93.400(a), (d).

<sup>22</sup> *Id.* § 93.400.

<sup>23</sup> *Id.* § 50.606.

<sup>24</sup> *Id.* § 93.407.

debarment from receiving federal funds.<sup>25</sup> HHS may also “seek to recover PHS funds spent in support of the activities that involved research misconduct.”<sup>26</sup>

### III. ANALYSIS

The idea of penalizing scientific investigators for “serious noncompliance” with FCOI disclosure requirements by formally tagging such behavior with the academic scarlet letter of research misconduct is intriguing. But my analysis of current law and policy concludes that an effort by PHS funding-agencies to treat failure to disclose FCOI *in itself* as research misconduct is unlikely to be sustained by the courts under existing federal regulations. Four features of administrative law regulating research bias and objectivity would support a legal challenge to PHS regulatory action: (a) the full definition of research misconduct under current regulations; (b) the regulatory standards for a finding of “research misconduct”; (c) the intent behind the 2004–2005 rulemaking process for revised research misconduct policies across federal agencies; and (d) the regulatory structure created by the 2004–2005 rulemaking process.

#### *A. Definition of Research Misconduct Under 42 C.F.R. § 93.103*

To refresh, under PHS regulations, “[r]esearch misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.”<sup>27</sup> In Botkin’s view, an investigator’s failure to disclose significant financial relationships with entities related to the investigator’s research constitutes research misconduct as defined by 42 C.F.R. § 93.103(b) because such nondisclosure could be deemed “falsification.”<sup>28</sup> However, when the definitions provided for the terms that fall within the definition of “research misconduct” under 42 C.F.R. § 93.103 are considered, it seems unlikely a court would interpret 42 C.F.R. § 93.103 broadly enough to encompass failure to disclose FCOI in grant proposals or publications.<sup>29</sup>

#### *1. Failure to Disclose FCOI Is Unlikely to Be “Falsification”*

Under 42 C.F.R. § 93.103(b), “[f]alsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.”<sup>30</sup> There are two primary challenges for addressing failure to disclose FCOI as “falsification” under

---

<sup>25</sup> *Id.* § 93.407.

<sup>26</sup> *Id.* § 93.407(b).

<sup>27</sup> *Id.* § 93.103.

<sup>28</sup> *Id.* § 93.103(b); Botkin, *supra* note 2, at 2308.

<sup>29</sup> 42 C.F.R. § 93.103 (2019).

<sup>30</sup> *Id.* § 93.103(b).

42 C.F.R. § 93.103(b). First, the definition of “falsification” in § 93.103(b) provides for specific acts and outcomes that must be shown to constitute “falsification” rather than a general showing, as described by Botkin, of “offer[ing] a false picture of the research environment.”<sup>31</sup> Second, “falsification” is demonstrated by specified acts and outcomes that have actually occurred. The definition does not seem to allow for a finding when circumstances exist which may influence the conduct and reporting of research.<sup>32</sup>

(a) *Misrepresentation of the “Research Environment” Is Not “Falsification”*

According to Botkin, significant failure to disclose FCOI is “falsification” because when “an investigator provides an incomplete or inaccurate account of his or her affiliations,” the investigator “offers a false picture of the research environment to funders, the research institution, research participants, and readers of the report.”<sup>33</sup> But 42 C.F.R. § 93.103(b) provides a definition of “falsification” that is more specific, and more restrictive, than Botkin’s conception.<sup>34</sup> Under 42 C.F.R. § 93.103(b), “falsification” is a set of specific actions: “manipulating research materials, equipment, or processes, or changing or omitting data or results” that have consequences for “the research” as “represented in the research record.”<sup>35</sup> Under 42 C.F.R. § 93.222, “research” is defined as “a systematic experiment, study, evaluation, demonstration or survey . . . .”<sup>36</sup> Further, “Research record” is defined by 42 C.F.R. § 93.224 as “the record of data or results that embody the facts resulting from scientific inquiry.”<sup>37</sup> The detailed regulatory definition of “falsification” is at odds with a general characterization of the “research environment,” even one that is biased toward specific findings by an FCOI not managed by an institutional plan.

Moreover, the 42 C.F.R. § 93.103(b) definition of “falsification” requires manipulation of “materials,” “equipment,” “processes,” or changing or omitting

---

<sup>31</sup> *Id.* § 93.103(b); Botkin, *supra* note 2, at 2308.

<sup>32</sup> 42 C.F.R. § 93.103(b).

<sup>33</sup> Botkin, *supra* note 2, at 2308.

<sup>34</sup> 42 C.F.R. § 93.103(b).

<sup>35</sup> *Id.* § 93.103(b).

<sup>36</sup> *Id.* § 93.222 (“Research means a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied.”).

<sup>37</sup> *Id.* § 93.224 (“Research record means the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to HHS or an institutional official by a respondent in the course of the research misconduct proceeding.”).

collected data or results generated by analysis of data.<sup>38</sup> In order for this definition to cover failure to disclose FCOI upon submission of a sponsored research proposal or publication, regulators would need to classify grant proposals and publications as “research materials.”<sup>39</sup> Neither 42 C.F.R. § 93.103 nor the Part 93 subpart B definitions of special terms provides a definition of “research materials” or “materials.”<sup>40</sup> The lack of a regulatory definition of “materials” creates uncertainty about whether an administrative law judge or a court would uphold an enforcement action that turned on regulators’ interpretation of the term.

*(b) Existence of Risk Is Insufficient for “Falsification” Under 42 C.F.R. Part 93*

The second impediment to treating failure to disclose FCOI as “falsification” is that the regulatory definition of “falsification,” requires that the specified acts and the effect on the research have actually occurred. Botkin’s argument, however, is that if the noncompliance is serious enough, the failure to disclose should *in itself* be deemed research misconduct because of the *risk* to the integrity of the research process.<sup>41</sup> In particular, Botkin sees the “falsification” of inaccurate FCOI disclosures as “relevant to proposing, performing, and reporting research results” because “[a] failure to disclose an external financial relationship *may* influence . . . how the research is conducted . . . and the reporting of the results.”<sup>42</sup> In evaluating whether failure to disclose FCOI rises to the level of research misconduct, Botkin does not see this as an inquiry that depends on whether there were effects on conduct or reporting of the research.<sup>43</sup>

The “risk” approach relies on Botkin’s contention that a finding of research misconduct can be made if the failure to disclose was “a significant departure from accepted practices of the relevant scientific community.”<sup>44</sup> Botkin’s argument treats this standard, contained in 42 C.F.R. § 93.104, as an alternate definition of research misconduct. But it is, instead, one of the standards that governs a finding of research

---

<sup>38</sup> *Id.* § 93.103(b); *see also* David B. Resnick, Commentary, *Is It Time to Revise the Definition of Research Misconduct?*, 26 ACCOUNTABILITY IN RES. 123, 128 (2019) (“While not disclosing a COI may inaccurately represent the research, it does not involve manipulation of materials, equipment, or processes, or changing or omitting data. If not disclosing a significant COI is to be viewed as a form of misconduct, it should be regarded as a separate category of misbehavior, not as falsification.”).

<sup>39</sup> 42 C.F.R. § 93.103(b) (2019).

<sup>40</sup> *Id.* § 93.103; *id.* §§ 93.200–227 (Subpart B fails to include “research materials” or “materials” in the definition section at all).

<sup>41</sup> Botkin, *supra* note 2, at 2307.

<sup>42</sup> *Id.* at 2308 (emphasis added).

<sup>43</sup> *Id.*

<sup>44</sup> *Id.* (referring to the standards for a finding of research misconduct promulgated at 42 C.F.R. § 93.104).



misconduct based on actions delineated in 42 C.F.R. § 93.103.<sup>45</sup> So, both in the adoption of a risk-based standard and the repurposing of an existing standard as an action constituting research misconduct, Botkin's proposed approach is markedly different than the current law.

Botkin's approach is also different than the mandate for handling FCOI under 42 C.F.R. Part 50. Under 42 C.F.R. Part 50, failure to disclose FCOI itself does not automatically trigger sanctions.<sup>46</sup> Instead, identification of noncompliance initiates an investigation into whether the now-identified FCOI was accompanied by "falsification" as defined under the research misconduct regulations.<sup>47</sup> This two-stage inquiry reinforces the conclusion that a finding of research misconduct is based on occurrence of specific behaviors during the conduct of the research while FCOI disclosure noncompliance represents a risk that such acts will occur.

## 2. *Regulatory Guidance Is Not Clearly Supportive of Addressing FCOI as "Falsification"*

Botkin points to regulatory guidance to support his argument for a broader reading of the definition of research misconduct and, in particular, falsification.<sup>48</sup> According to Botkin, regulatory guidance "makes clear that a misrepresentation of any investigator's credentials or publications in grant applications may constitute a fabrication or falsification in proposing research."<sup>49</sup> Botkin views "this situation [as] analogous to misrepresenting financial relationships."<sup>50</sup>

However, the cited guidance, while referring to "credentials and publications" in the phrasing of a question, states that it is "misrepresentation of a researcher's *qualifications or ability to perform the research* [that] may constitute falsification or fabrication in proposing research."<sup>51</sup> As with the regulatory definition of "falsification," the focus is on the conduct of the research. And even in the scenario here, where a researcher misrepresents their qualifications, the language of "may" rather than "shall" dictates that an additional inquiry must be undertaken into effects on the research results. This approach parallels the two-stage inquiry established in

---

<sup>45</sup> *Id.* at 2308; 42 C.F.R. §§ 93.103–104 (2019).

<sup>46</sup> *See* 42 C.F.R. § 50.606.

<sup>47</sup> *Id.* §§ 50.606, 93.103.

<sup>48</sup> Botkin, *supra* note 2, at 2308.

<sup>49</sup> *Id.* (citing Federal Research Misconduct Policy, 65 Fed. Reg. 76,260, 76,261 (Dec. 6, 2000)). Botkin lists the Office of Research Integrity as the institutional author of the Notice of Final Policy cited in his article. However, although the Notice of Final Policy is published on the ORI website, the Federal Research Misconduct Policy referenced was issued by the Office of Science and Technology Policy (OSTP) rather than ORI or another HHS office or agency. ORI may, of course, refer to OSTP guidance on a federal policy in ORI decisions. *Id.*

<sup>50</sup> *Id.*

<sup>51</sup> Federal Research Misconduct Policy, 65 Fed. Reg. 76,260, 76,261 (Dec. 6, 2000) (emphasis added).

the FCOI regulations; a finding of FCOI disclosure noncompliance initiates a review of the investigator's research, which may lead to a finding of research misconduct.<sup>52</sup> Therefore, regulatory guidance currently provides, at best, a weak indication that regulators are prepared to treat FCOI disclosure noncompliance in itself as sufficient for a finding of research misconduct.

*B. Regulatory Standards for a Finding of "Research Misconduct"*

The PHS regulations also provide the standards for a finding of research misconduct as defined in 42 C.F.R. § 93.103.<sup>53</sup> Under 42 C.F.R. § 93.104, a finding of research misconduct requires: "(a) There be a significant departure from accepted practices of the relevant research community; and (b) The misconduct be committed intentionally, knowingly, or recklessly; and (c) The allegations be proven by a preponderance of the evidence."<sup>54</sup> This Note focuses its discussion on the former two standards established in the PHS regulations. Setting aside for a moment the legal question of whether the research misconduct regulations do cover FCOI nondisclosure, this section analyzes whether the standards can be practically applied to instances of "serious noncompliance" with FCOI disclosure requirements.

*1. There Is No Generally Agreed Upon Practice Among Investigators for FCOI Disclosure*

Under PHS regulations, the first standard for a finding of research misconduct is there must "be a significant departure from accepted practices of the relevant research community."<sup>55</sup> In traditional research misconduct investigations conducted by PHS, ORI makes comparisons between the conduct of the PHS-funded investigator during the research process and the standard research and publication practices in the investigator's scientific field.<sup>56</sup> For example, in *Krishna Murthy*, the administrative law judge (ALJ) rejected the respondent-investigator's argument that "his errors are commonplace in the research community—that everyone makes and publishes errors like the ones that he made and published."<sup>57</sup> The ALJ concluded the respondent conducted his research in a manner that "significantly departed" from the accepted practices of protein scientists to use "validation tools . . . [to] verify the accuracy of [their] protein model" and then, adhering to an "honor system," refrain

---

<sup>52</sup> 42 C.F.R. §§ 50.604–605(a)(3)(ii)(A) (2019); *see also supra* Part II.

<sup>53</sup> 42 C.F.R. § 93.103.

<sup>54</sup> *Id.* § 93.104.

<sup>55</sup> *Id.* § 93.104.

<sup>56</sup> *See, e.g., Krishna Murthy*, DAB No. CR5007, at \*1 (H.H.S. Jan. 19, 2018), 2018 WL 8368300 (amended recommended decision) (granting summary judgment upon determining that a PHS-funded investigator, who "falsified and/or fabricated 11 protein structures and reported them in nine publications and in twelve entries to an entity known as the Protein Data Bank (PDB)," had engaged in research misconduct).

<sup>57</sup> *Id.* at \*2.

from depositing models of protein structures into the Protein Data Bank that fail the validation process.<sup>58</sup> To translate this analysis to instances of noncompliance with FCOI disclosure requirements, there must be a generally agreed upon FCOI disclosure practice among the scientific research community to which research institutions and PHS agencies could compare the conduct of a particular investigator.

As one exploratory effort to identify whether a consensus about FCOI disclosure exists outside of the regulatory mandate for annual FCOI reporting to the funding agency for PHS-funded investigators, I catalogued current FCOI disclosure policies at a subset of major research universities.<sup>59</sup> In a 2019 review of FCOI policies at Pac-12 universities, nine of the twelve universities did not have a policy requiring FCOI disclosure for investigators whose research was not sponsored by external grants.<sup>60</sup> In 2019, the three universities that had an annual FCOI disclosure requirement for all university faculty were: Stanford University, University of Colorado Boulder (UC-Boulder), and Oregon State University (OSU).<sup>61</sup> In July 2020, the University of Utah joined this group by revising its policy to include a requirement for FCOI disclosure by faculty upon hire and at the start of each academic year.<sup>62</sup> Yet, even within this small subgroup, there is variation. Stanford and UC-Boulder's policies include broad language that requires disclosure of conflicts involving "professional obligations to the University" and "any university responsibility," respectively.<sup>63</sup> OSU's annual attestation requirement for faculty is

---

<sup>58</sup> *Id.* at \*3.

<sup>59</sup> *Cf.* National Institute of Health, NIH Office of Extramural Research, *NOT-OD-11-109, Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors* (Aug. 22, 2011), <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-109.html> [<https://perma.cc/GQ4P-R9KK>] (describing major changes to HHS regulations governing FCOI disclosure requirements for PHS-funded investigators and their research institutions).

<sup>60</sup> Tammy M. Frisby, *Pac-12 University Policies Governing Individual FCOI Disclosure Timing* (May 10, 2019) (working paper) (on file with author).

<sup>61</sup> *Id.*; *see also* STAN. UNIV., RESEARCH POLICY HANDBOOK, 4.1 FACULTY POLICY ON CONFLICT OF COMMITMENT AND INTEREST, <https://doresearch.stanford.edu/policies/research-policy-handbook/conflicts-commitment-and-interest/faculty-policy-conflict-commitment-and-interest> [<https://perma.cc/3ADB-5LAK>] (last visited June 7, 2020); UNIV. OF COLO.-BOULDER, CONFLICT OF INTEREST AND CONFLICT OF COMMITMENT POLICY (2019), <https://www.colorado.edu/researchinnovation/coi/policies-procedures> [<https://perma.cc/N8FK-ZXFM>]; OR. STATE UNIV., OSU POLICY ON RESEARCH CONFLICTS OF INTEREST (2017), <https://research.oregonstate.edu/coi/about-conflict-interest-program/policy-research-conflicts-interest> [<https://perma.cc/QY6B-GA6F>]. *But see* U.C. BERKELEY, PPSM-82: CONFLICT OF INTEREST (2020) <https://policy.ucop.edu/doc/4010421/PPSM-82>, [<https://perma.cc/Z4JT-Q4LN>] (no policy provision requiring annual attestation of FCOI disclosure for faculty who are not conducting sponsored-project research).

<sup>62</sup> UNIV. OF UTAH, POLICY 1-006 INDIVIDUAL FINANCIAL CONFLICT OF INTEREST, III.A.1.a.i (2020), <https://regulations.utah.edu/general/1-006.php> [<https://perma.cc/HBE9-NJTV>].

<sup>63</sup> STAN. UNIV., *supra* note 61; UNIV. OF COLO.-BOULDER, *supra* note 61.

expressly limited to conflicts arising from a faculty member's research.<sup>64</sup> The University of Utah policy appears to stake out a middle ground by defining "financial relationship" as "any financial interest or relationship . . . that reasonably appears to be related to an Investigator's or Employee's responsibilities to the University, as those responsibilities are defined by the Investigator's or Employee's department or job description."<sup>65</sup>

The fact that annual FCOI disclosure requirements for non-PHS-funded researchers are the minority policy among Pac-12 universities suggests that the academic research community in general—despite the legally mandated annual reporting for PHS-funded investigators—does not regard regularly updated FCOI disclosure as an "accepted practice." We might assume for the sake of argument that there is a nascent but developing community standard. Yet, at best, there would currently be a wide—although narrowing—range of "accepted practices."

Eventually, we may be able to recognize that meaningful agreement on FCOI has emerged among the research community. But in its current state, the lack of a clearly articulated community standard provides grounds for a PHS-funded investigator to mount a legal challenge to an agency determination that elevates failure to disclose FCOI to research misconduct. Without evidence to support the contention that "the relevant research community" has its own "accepted practices" on proper FCOI disclosure independent of what the law makes PHS-funded investigators do, an agency action treating noncompliance with FCOI disclosure requirements as research misconduct is vulnerable to a challenge that the decision was "arbitrary and capricious."<sup>66</sup>

## *2. The Culpability Standard for Research Misconduct Aligns with Treating "Serious Noncompliance" with FCOI as Research Misconduct*

In contrast to the definition of research misconduct and the standard of "accepted practices," the existing culpability standard does not present an obstacle to applying existing research misconduct rules to regulate FCOI disclosure. Indeed, the culpability standard aligns with the objective of treating "serious noncompliance" with FCOI disclosure as research misconduct. Further, the standard, which is higher than ordinary negligence, would not assign liability in

---

<sup>64</sup> OR. STATE UNIV., *supra* note 61.

<sup>65</sup> UNIV. OF UTAH, *supra* note 62, at II.G.

<sup>66</sup> 42 C.F.R. § 93.104 (2019). Under the Administrative Procedures Act, courts are directed to "hold unlawful and set aside agency action, findings, and conclusions" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A) (2018). However, courts are to grant deference to executive agency actions in their review of procedural correctness and "[are] not to substitute [the court's] judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

cases in which an investigator makes an honest mistake or is merely careless in their recordkeeping and disclosure.<sup>67</sup>

Botkin does not define “serious noncompliance.”<sup>68</sup> This Note proposes the following working definition: failure to disclose significant financial interests that (a) occurs despite notice of the obligation to report and (b) is characterized by either (1) a pattern of nondisclosure or (2) an incident of nondisclosure that creates an appearance of corruption to a reasonable layperson. Given that Botkin’s proposal is not motivated by the desire to penalize absent-minded professors, some level of culpability is called for.<sup>69</sup> Setting the required mental state at a level above ordinary negligence would further reduce the likelihood of mistakenly treating honest errors, inadvertent oversights, and poor paperwork management skills as acts that are deserving of significant sanctions, such as limitations on federal funding that support the investigator’s public health research.<sup>70</sup>

The mental state that must be shown for a finding of research misconduct under PHS regulations is the conduct must be “committed intentionally, knowingly, or recklessly.”<sup>71</sup> In *Brodie v. U.S. Department of Health and Human Services*,<sup>72</sup> the district court was presented with the issue of the proper culpability standard for research misconduct that occurred from 1999–2002, under an earlier version of the HHS regulations that were silent on the required mental state, except to exclude “honest error.”<sup>73</sup> The court’s decision, which is consistent with the current culpability thresholds, provides a helpful delineation of conduct that rises to the required standard and that which does not.<sup>74</sup>

In *Brodie*, PHS-funded molecular biologist, Scott Brodie, brought an action under the Administrative Procedures Act (APA) challenging an HHS ALJ’s ruling debaring him from receiving federal research funding for seven years based on the finding that the investigator had committed research misconduct.<sup>75</sup> In 2008, ORI filed a charge of research misconduct against Brodie following the conclusion of a research misconduct investigation by Brodie’s research institution, the University of

---

<sup>67</sup> See 42 C.F.R. § 93.104.

<sup>68</sup> Botkin, *supra* note 2, at 2308.

<sup>69</sup> See *id.* at 2307 (“It is time to strengthen institutional COI policies by considering the intentional or negligent failure to disclose significant financial relationships relevant to the conduct of research to be research misconduct.”).

<sup>70</sup> 42 C.F.R. § 93.407 (governing PHS-imposed sanctions for research misconduct).

<sup>71</sup> *Id.* § 93.104.

<sup>72</sup> 796 F. Supp. 2d 145 (D.D.C. 2011).

<sup>73</sup> *Id.* at 148, 151 (quoting 42 C.F.R. § 50.102 (2002)) (“Misconduct or Misconduct in Science means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.”); see also 42 C.F.R. § 93.104 (2019) (specifying standards for a finding of research misconduct).

<sup>74</sup> *Brodie*, 796 F. Supp. 2d at 151–53.

<sup>75</sup> *Id.* at 148.

Washington, which resulted in termination of Brodie's employment.<sup>76</sup> In a hearing before an ALJ, Brodie argued the ORI had not used the proper culpability standard in its determination that he had committed research misconduct when he submitted grant applications, published scientific articles, or made professional presentations using false or fabricated images.<sup>77</sup> In district court, Brodie argued that the ALJ's decision upholding the ORI's finding was "arbitrary and capricious" because the ALJ applied an improperly low standard of culpability, that of recklessness, in making its determination.<sup>78</sup>

The district court upheld the ALJ's determination that "the new definition of misconduct was simply a 'clarification' of the older definition of misconduct."<sup>79</sup> Assigning liability for recklessness, which was now stipulated as a sufficient mental state under the new regulations, was also consistent with the earlier regulatory language because recklessness encompasses "conduct [that] is not the product of 'honest error.'"<sup>80</sup>

For purposes of administering current HHS regulations, the *Brodie* decision speaks to the showing that must be made to establish that conduct was reckless and not "honest error."<sup>81</sup> Citing a different HHS Departmental Appeals Board decision on a research misconduct charge, *Sharma*,<sup>82</sup> the district court stated that recklessness could be established when "statements are made with knowledge that they would mislead the reader."<sup>83</sup> This type of conduct, "as opposed to mere negligence, constituted misconduct."<sup>84</sup> As applied to the facts in *Brodie*, the court concluded: "Publication of false or fabricated images with indifference to the truth of [their] contents is conduct done with knowledge that it would mislead the reader. Such conduct is not the product of honest error."<sup>85</sup> The district court upheld the ALJ's determination that a showing of "indifference to the truth," as distinct from simple negligence, was sufficiently supported by the "mass and pattern of the false images and the nature of the false images—for which the alterations fundamentally [changed] the description and meaning of [the] contents."<sup>86</sup>

The current culpability standard for research misconduct is an appropriate one for identifying bad actors related to FCOI nondisclosure, both in terms of the mental state required and the showing necessary to establish the mental state.

First, regarding the mental state, the policy concern is not that well-intentioned investigators might fail to stay on top of their FCOI reporting paperwork or neglect

---

<sup>76</sup> *Id.*

<sup>77</sup> *Id.* at 149–150.

<sup>78</sup> *Id.* at 150–51.

<sup>79</sup> *Id.* at 152.

<sup>80</sup> *Id.*

<sup>81</sup> *Id.*

<sup>82</sup> DAB No. 1431 (H.H.S. Aug. 6, 1993), 1993 WL 742551.

<sup>83</sup> *Brodie*, 796 F. Supp. 2d at 151 (citing *Sharma*, DAB No. 1431, at \*8).

<sup>84</sup> *Id.* at 151.

<sup>85</sup> *Id.* at 152 (alteration in original) (internal quotation marks omitted).

<sup>86</sup> *Id.* at 151 (alteration in original) (citation omitted) (internal quotation marks omitted).

to proofread the disclosures statement in an academic journal article. These oversights could be characterized as ordinary negligence. A higher culpability standard than mere negligence would target the regulatory scheme at bad actors who are, at the least, willfully indifferent to risks to research integrity.

Second, the *Brodie* standard for the showing of recklessness, the lowest culpability level under existing regulations, should effectively distinguish between sneaky bad actors and mere negligence in FCOI disclosure as well as it does in traditional research misconduct adjudications. As found in *Brodie*, the standard of “indifference to the truth” could be demonstrated by a pattern of nondisclosure that occurs even when an investigator receives repeated notice of the obligation to disclose.<sup>87</sup> But a pattern may not be a necessary showing. Indifference, and the *Brodie* corollary that conduct would be “done with knowledge that it would mislead” consumers of the research,<sup>88</sup> may be even clearer in singular instances of failure to report FCOI that create an obvious appearance of corruption (e.g., receipt of large speaking fees from a pharmaceutical company that manufactures the drug evaluated in the investigator’s published journal article).

So, in spite of the other challenges for treating FCOI nondisclosure as research misconduct under the current regulations, there are ready legal standards for culpability that could be applied. These standards and the accompanying showings would assign liability where reformers like Botkin would like to see accountability. Moreover, the standards would not stymie the research programs of investigators who may need to be more diligent but are not blameworthy underminers of research integrity.

### *C. Agency Rulemaking in Response to Federal Policy for Research Misconduct*

HHS’s latitude to modify the PHS definition of “research misconduct” is constrained by the Department’s own history of rulemaking on the subject. But,

---

<sup>87</sup> *Id.*; see also Krishna Murthy, DAB No. CR5007, at \*5 (H.H.S. Jan. 19, 2018), 2018 WL 8368300 (concluding that PHS-funded investigator was at the least “[recklessly] indifferent to what his experimental data actually showed” on the grounds that the respondent’s protein models contained “gross errors” and there was “a pattern to [r]espondent’s conduct” of repeatedly publishing or depositing into databanks data corrupted by the same type of errors. The ALJ contrasted the nature of respondent’s conduct with ordinary negligence: “Everyone makes mistakes from time to time and perfection is not a standard for judging any research’s work pursuant to the regulations governing misconduct in science. A scientist might deposit a protein model in the [Protein Data Bank] that contains innocent or trivial errors without intending to defraud and without indifference to the truth of his or her submission. But, no honest researcher would deposit or publish so many false models or so much false data as Respondent published or deposited. The sheer number of false submissions by [r]espondent over the course of nearly a decade is as damning as is the character of what he deposited and published.”).

<sup>88</sup> *Brodie*, 796 F. Supp. 2d at 151 (citing Sharma, DAB No. 1431, at \*8 (H.H.S. Aug. 6, 1993), 1993 WL 742551).

before cataloging those obstacles, we should recognize that the HHS Secretary has the statutory authority to establish the definition of “research misconduct” for Public Health Service research. Under 42 U.S.C. § 289(a)(3)(A), the Secretary is granted the discretion to define “research misconduct”: “The Secretary shall by regulation establish a definition for the term ‘research misconduct’ for purposes of this section.”<sup>89</sup> Assessing the Secretary’s authority more broadly, under 42 U.S.C. § 241(a):

The Secretary shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promoting the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man . . . .<sup>90</sup>

So, in statutory language related to the scope of the HHS Secretary’s authority, there is, respectively, an express specific grant to define research misconduct and a general grant that both support the Secretary’s authority to establish a PHS Policy that “serious noncompliance” with FCOI disclosure may be treated as “research misconduct.”

That said, HHS rulemakers may be constrained by the regulatory history of the current PHS research misconduct regulations, which were drafted during a 2004–2005 rulemaking process in order to bring PHS regulations into conformity with the government-wide Federal Policy on Research Misconduct issued by the White House Office of Science and Technology Policy (OSTP) on December 6, 2000.<sup>91</sup> While HHS made some modifications to the OSTP rule, such as excluding authorship disputes from the definition of plagiarism, the HHS policy largely adopted the OSTP definition of research misconduct, as well as the elements necessary for a finding of research misconduct.<sup>92</sup>

In the Supplementary Information provided with the publication of the Public Health Services Policies on Research Misconduct Final Rule, HHS recognized the “OSTP goal of a more uniform, Federal-wide approach.”<sup>93</sup> Furthermore, in the Department’s response to “Significant Comments Not Resulting in Changes” regarding the definition of “research misconduct,” HHS rulemakers expressly addressed their intent to adhere closely to the OSTP policy.<sup>94</sup> As stated in the Final Rule: “Given the careful consideration that has been given to this definition and the

---

<sup>89</sup> 42 U.S.C. § 289(a)(3)(A) (2018).

<sup>90</sup> 42 U.S.C. § 241(a) (2018).

<sup>91</sup> Public Health Services Policies on Research Misconduct, 70 Fed. Reg. 28,370, 28,370 (May 17, 2005) (to be codified at 42 C.F.R. pts. 50, 93) (citing Federal Research Misconduct Policy, 65 Fed. Reg. 76,260 (Dec. 6, 2000)).

<sup>92</sup> *Id.* at 28,370.

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

<sup>94</sup> *Id.* at 28,377.



value of a uniform government-wide definition, we are adopting the definition as it was proposed.”<sup>95</sup> HHS’s prioritization of consistency with OSTP Federal Policy is reinforced by its decision to address, as the first question in the question-and-answer section of the Final Rule, an inquiry about whether the HHS rule was consistent with “the goal of the OSTP Federal Policy on Research Misconduct to provide a more uniform Federal-wide approach.”<sup>96</sup> Taken together, these statements convey the intent of HHS rulemakers to draft a research misconduct rule that does not deviate from Federal Policy. Accordingly, unilateral action by HHS to re-interpret research misconduct to cover FCOI would represent a deviation from Federal Policy that, whatever its merits for promoting research integrity, would be a significant departure from the intent of HHS rulemakers to bring uniformity to this area of administrative law during the 2004–2005 rulemaking process. If HHS attempts to widen its conception of research misconduct under the current rules, strategic respondents in enforcement actions will question how the agency claims to justify its new-found desire to exempt itself from the uniform policy across the executive branch.

Furthermore, the definition of research misconduct adopted with the revised regulation removed language that supported a broader reading. Under the version of 42 C.F.R. § 50.102 in effect at the time of the rulemaking, “‘Misconduct’ or ‘Misconduct in Science’ meant fabrication, falsification, plagiarism, *or other practices* that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research.”<sup>97</sup> The decision to remove “other practices” from the definition of research misconduct supports an interpretation that rulemakers intended to narrow and precisely define actions that constitute research misconduct.<sup>98</sup>

#### *D. Structural Indications that FCOI Are Distinct from Research Misconduct*

Another possible limitation on the treatment of FCOI nondisclosure as research misconduct under 42 C.F.R. § 93.103 is the structure of the HHS regulations governing FCOI disclosure and research misconduct. There are two primary features of the codified regulations that support the position that HHS rulemakers viewed FCOI disclosure noncompliance as distinct from research misconduct: (1) the relocation of the research misconduct rules during the 2004–2005 rulemaking process; and (2) the absence of language in either the FCOI or research misconduct

---

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

<sup>96</sup> *Id.* at 28,379.

<sup>97</sup> 42 C.F.R. § 50.102 (2005) (emphasis added).

<sup>98</sup> See Resnick, *supra* note 38, at 123 (discussing that the OSTP Federal Policy that initiated the HHS rulemaking process “eliminated the category ‘other serious deviations,’ which had been used by the National Institutes of Health (NIH) and other agencies. OSTP decided to not include the ‘other serious deviations’ category in the definition of [research] misconduct because it judged it to be vague, all encompassing, and difficult to enforce . . . .”) (citations omitted).

rules that indicates that the FCOI and research misconduct rules might work in tandem to address certain violations of research integrity.

*1. Separation of FCOI and Research Misconduct Rules During the 2004–2005 Rulemaking Process*

First, the FCOI and research misconduct rules are intentionally located in different Parts of the HHS regulations. The 2004–2005 HHS rulemaking process removed the research misconduct rules from subpart A of 42 C.F.R. Part 50 while leaving the FCOI rules, in their entirety, in subpart F of that same Part.<sup>99</sup> The HHS Final Rule for the revised research misconduct regulations promulgated at 42 C.F.R. Part 93 describes the new regulations as the “new, *more comprehensive* part 93.”<sup>100</sup> If HHS rulemakers understood any portion of the FCOI rules in subpart F of 42 C.F.R. Part 50 to be relevant to regulation of “research misconduct,” it would seem to run counter to the design of a “more comprehensive” regulatory scheme to sever the new regulations from existing related rules. Further, the public comments and the agency’s responses contained in the HHS Final Rule do not mention investigator conflicts of interest.<sup>101</sup> This lack of public discussion during the 2004–2005 rulemaking process about how the revised research misconduct rules and existing FCOI regulations might support one another—or conflict in any way—suggests that both stakeholders and the agency saw research misconduct and FCOI as distinct types of conduct governed by separate rules.

*2. Absence of Language Establishing a Relationship Between FCOI and Research Misconduct*

The argument for treating FCOI of any severity as research misconduct is further weakened by the absence of language in either 42 C.F.R. Part 50 or Part 93 that supports the inference that some conduct covered by the FCOI rules might also be covered by the research misconduct rules. Prior to the 2004–2005 HHS rulemaking process, the FCOI rules located in subpart F of 42 C.F.R. Part 50 did not contain any connecting language to the research misconduct rules located in subpart A of that same Part.<sup>102</sup> Even more salient, HHS rulemakers did not add such language to either Part during the 2004–2005 rulemaking process when the research misconduct rules were removed from 42 C.F.R. Part 50 and relocated to 42 C.F.R.

---

<sup>99</sup> Public Health Services Policies on Research Misconduct, 70 Fed. Reg. 28,370, 28,370 (May 17, 2005) (to be codified at 42 C.F.R. pts. 50, 93) (citing Federal Research Misconduct Policy, 65 Fed. Reg. 76,260 (Dec. 6, 2000)); 42 C.F.R. Part 50, subparts A, F (2005); *id.* Part 50, subpart F (2019).

<sup>100</sup> Public Health Services Policies on Research Misconduct, 70 Fed. Reg. at 28,370 (emphasis added).

<sup>101</sup> *Id.* at 28,370–28,381.

<sup>102</sup> 42 C.F.R. Part 50, subparts A, F (2005).

Part 93,<sup>103</sup> nor was connecting language added when the FCOI rules were revised in 2011.<sup>104</sup> The lack of connecting language between the FCOI rules left in 42 C.F.R. Part 50 and the research misconduct rules relocated to 42 C.F.R. Part 93 suggests that HHS rulemakers did not see a need to maintain a relationship between the two sets of rules. The 2004–2005 HHS rulemakers did not, for example, include language to the effect that FCOI nondisclosure may rise to the level of research misconduct covered by 42 C.F.R. Part 93.

#### IV. RECOMMENDATIONS

As the preceding Part lays out, a PHS-funded investigator could bring a viable legal challenge to an effort by a PHS funding-agency to treat failure to disclose FCOI in itself as research misconduct. Whether a charged investigator used some or all of the definitional, standards-based, or structural and historical arguments about the existing regulations, the agency’s decision would be highly susceptible to being overruled by a district court as arbitrary and capricious. In short, it is unlikely that current PHS regulations governing research misconduct could be used to address “serious noncompliance” with FCOI disclosure requirements.

One possible reaction to this conclusion is that the PHS regulations should be revised to expressly cover at least the most egregious cases of FCOI nondisclosure under the research misconduct rules. While this course of regulatory reform is not entirely improbable, the rulemaking process might, of course, take years to produce a final rule if it was successful at all. Moreover, the HHS Office of Research Integrity, which has primary oversight of research misconduct, has issued no public statement that revision of the research misconduct regulations is on its rulemaking agenda.<sup>105</sup>

The question then presents itself: What actions could reasonably be taken, short of a call for a new HHS rulemaking process, to address “serious noncompliance” with FCOI disclosure requirements by a PHS-funded investigator?

The logical first stop is with research institutions, which bear the primary—and the frontline—responsibility for policing FCOI among PHS-funded investigators under current regulations.<sup>106</sup> Research institutions are permitted to establish more stringent internal standards for research misconduct than those provided by PHS regulations.<sup>107</sup> The PHS regulation on institutional standards expressly grants

---

<sup>103</sup> 42 C.F.R. Part 50, 93 (2006).

<sup>104</sup> 42 C.F.R. Part 50, subpart F (2012); *accord* 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) (to be codified at 42 C.F.R. pt. 50, 45 C.F.R. pt. 94) (final rule implementing changes to the PHS regulations governing FCOI disclosure, management, and oversight).

<sup>105</sup> HHS OFFICE OF RESEARCH INTEGRITY, <https://ori.hhs.gov/> [<https://perma.cc/9964-T8J8>] (last visited June 7, 2020).

<sup>106</sup> *See supra* Part II.

<sup>107</sup> 42 C.F.R. § 93.319(a) (2019).

independent enforcement authority to research institutions: “[A]n institution may find conduct to be actionable under its standards even if the action does not meet this part’s definition of research misconduct.”<sup>108</sup> The regulation reinforces the autonomy of research institutions to set and enforce their own, more expansive, standards for research misconduct by stipulating that research institutions are allowed to come to different findings than emerge from a parallel HHS investigation: “An HHS finding or settlement does not affect institutional findings or administrative actions based on an institution’s internal standards of conduct.”<sup>109</sup> Therefore, there is no clear regulatory barrier to research institutions taking it upon themselves to revise their own research misconduct policies to establish disciplinary procedures for FCOI disclosure noncompliance.

Research institutions may be reluctant to unilaterally adopt an internal standard for research misconduct that incorporates FCOI nondisclosure. Research institutions would be reasonably concerned about hampering the recruitment and retention of investigators who bring in millions of dollars in PHS-funding but also have significant FCOI from their connections to medical and pharmaceutical companies.

But research institutions should be motivated to coordinate across institutions to adopt more rigorous enforcement of and sanctions for “severe noncompliance” with FCOI disclosure.<sup>110</sup> If research institutions can successfully self-regulate, they may stave off any federal regulatory effort to fold FCOI nondisclosure into the HHS research misconduct rules.

The incentive for institutions to avoid federal rulemaking on this issue is clear—and very expensive. If FCOI nondisclosure is research misconduct under federal law, whistleblowers might test whether federal courts will allow *qui tam* suits under the False Claims Act (FCA) against PHS-funded research institutions for an investigator’s “severe noncompliance” with FCOI disclosure. Although the likely viability of such a suit is a legal question that deserves its own full analysis, suffice it to say for our purposes here that universities would risk significant legal liability.

The cautionary example of the extent of institutional FCA liability for investigator research misconduct under the federal rules became public news in 2016.<sup>111</sup> A former researcher at Duke University brought a *qui tam* claim against

---

<sup>108</sup> *Id.* § 93.319(a).

<sup>109</sup> *Id.* § 93.319(b).

<sup>110</sup> *Cf.* Resnick, *supra* note 38, at 133–34 (taking the position that “[w]hile the arguments for revising the federal definition [in the OSTP Federal Policy] of misconduct to include behaviors such as sexual harassment, sabotage, deceptive use of statistics, and failure to disclose a significant COI are not convincing at this point in time, the arguments for revising definitions used by other organizations, such as professional societies, universities, or journals, may be, because they have goals other than legally enforcing behavioral standards”).

<sup>111</sup> Alison McCook, *Whistleblower Sues Duke, Claims Doctored Data Helped Win \$200 Million in Grants*, SCIENCE (Sept. 1, 2016, 2:00 PM), <https://www.sciencemag.org/news/2016/09/whistleblower-sues-duke-claims-doctored-data-helped-win-200-million-grants> [<https://perma.cc/XQ67-8QRA>].

Duke alleging the university fraudulently accepted more than \$200 million in federal research funding when it oversaw another PHS-funded investigator who engaged in research misconduct, as defined under 42 C.F.R. § 50.<sup>112</sup> Under the FCA, Duke faced potential liability of up to three times the amount of any federal funds found to have been fraudulently obtained.<sup>113</sup> According to attorney Joel Androphy, who specializes in FCA litigation, the lawsuit against Duke “should scare all [research] institutions around the country.”<sup>114</sup> In 2019, Duke University reached a \$112.5 million settlement with the federal government.<sup>115</sup> Rather than being a stunningly expensive aberration, FCA litigators view the Duke suit as part of a growing trend of FCA claims against research institutions.<sup>116</sup> In the last decade, there have been high-profile FCA suits against University of Texas Health Sciences Center, Brigham and Women’s Hospital & Massachusetts General Hospital, and Weill Medical College of Cornell University, all involving claims of PHS-defined research misconduct.<sup>117</sup>

In the absence of coordinated action by research institutions to address serious failures to disclose FCOI through their institutional policies, the most effective approach for addressing the problem of noncompliance with institutional FCOI disclosure requirements may be through PHS agencies. Under current regulations, PHS funding-agencies have regulatory authority to penalize investigators for nondisclosure of FCOI.<sup>118</sup> PHS agencies could announce they will step up their enforcement of FCOI regulations under 42 C.F.R. § 50.606(b).<sup>119</sup> Under that provision, a PHS agency “may decide that a particular financial conflict of interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed . . . .”<sup>120</sup> However, relying on agency discretion for more vigorous enforcement of the less well-developed FCOI regulations is a far cry from the kind of active funding-agency involvement that may be required to reduce the influence of FCOI on medical and other public health research.

---

<sup>112</sup> *Id.* (reporting that a whistleblower alleged that the PHS-funded investigator and Duke University defrauded the federal government when the PHS-funded investigator “include[ed] fraudulent data in applications and reports involving more than 60 grants worth some \$200 million”); 42 C.F.R. Part 50 (2019).

<sup>113</sup> McCook, *supra* note 111.

<sup>114</sup> *Id.* (quoting Androphy in reporting that, “if successful, [the FCA suit against Duke] could ‘open the floodgates’ to other whistleblowing cases”).

<sup>115</sup> *Duke University Settles Research Misconduct Lawsuit for \$112.5 Million*, SCIENCE (Mar. 25, 2019, 1:50 PM), <https://www.sciencemag.org/news/2019/03/duke-university-settles-research-misconduct-lawsuit-1125-million> [<https://perma.cc/Z9YF-TNMW>]; *see also* McCook, *supra* note 111 (“Although recent court rulings suggest public universities may have some protection from qui tam suits because they are government entities, private institutions do not.”).

<sup>116</sup> McCook, *supra* note 111.

<sup>117</sup> *Id.*

<sup>118</sup> 42 C.F.R. § 50.606(b) (2019).

<sup>119</sup> *Id.* § 50.606(b).

<sup>120</sup> *Id.* § 50.606(b).

## V. CONCLUSION

It is unlikely that a court would find that current HHS regulations provide legal authority for PHS funding-agencies to address “serious noncompliance” with FCOI disclosure requirements as research misconduct. With one exception—the culpability standard for research misconduct—the administrative law governing bias and integrity in PHS-funded research does not support treating even the most serious cases of failure to disclose FCOI *in itself* as research misconduct in violation of PHS regulations. Indeed, there are at least four features of that law which would support a claim that an HHS action to treat FCOI nondisclosure as research misconduct was “arbitrary and capricious.” First, “serious noncompliance” with institutional FCOI disclosure requirements does not fall within the definition of “research misconduct” under 42 C.F.R. § 93.103. Second, one of the regulatory standards for a finding of research misconduct rests on a comparison with the “accepted practices” within the “relevant research community,” and there is currently no discernable consensus on FCOI disclosure requirements among major research institutions sufficient to establish clear parameters of “accepted practices.” Third, the intent behind the 2004–2005 rulemaking process that revised research misconduct policies across agencies of the federal government, including NIH, was to create a uniform federal policy on research misconduct—a historical legacy that may throw up legal constraints to any agency’s unilateral effort to reshape the contours of administrative actions for research misconduct. Fourth, the regulatory structure within Title 42 of the C.F.R. that was created by the 2004–2005 rulemaking process supports the conclusion that HHS rulemakers saw FCOI nondisclosure as distinct from research misconduct.

Short of new HHS rulemaking, there are viable options under current PHS research misconduct and FCOI disclosure rules to pursue more aggressive responses to “serious noncompliance” with FCOI disclosure. Research institutions are permitted to establish—and enforce—more stringent internal standards for research misconduct than those provided by PHS regulations. Although individual institutions may be reluctant to risk putting themselves at a competitive disadvantage in attracting top researchers by unilaterally adopting more stringent FCOI disclosure requirements, the emerging legal risk of False Claims Act (FCA) lawsuits could spur collective action. In the interest of reducing their legal exposure to FCA claims under HHS research misconduct regulations, institutions may decide they are better off coordinating on self-regulation of FCOI. Otherwise, lawmakers and regulators—perhaps spurred by high profile incidents like Baselga at Memorial Sloan Kettering—may decide to step in where institutions neglect to tread. In the meantime, the best that those concerned with the impact of FCOI on research integrity can hope for may be PHS agencies becoming more active in using their authority to review FCOI nondisclosure as a backstop to institutional inaction.