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Is it Time to Revise the Definition of Research Misconduct?

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Abstract

US federal policy defines research misconduct as fabrication of data, falsification of data, or plagiarism (FFP). In recent years, some have argued or suggested that the definition of research misconduct should also include sexual harassment, sabotage, deceptive use of statistics, and failure to disclose a significant conflict of interest. While the arguments for revising the definition of misconduct used by federal agencies to include misbehaviors other than FFP 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. Since these other organizations play an important role in promoting integrity in science and deterring unethical behavior, they may consider adopting definitions of misconduct that extend beyond FFP. Debates about the definition of research misconduct are a normal and healthy part of broader discussions about integrity in science and how best to promote it. These debates should continue even if the federal definition of misconduct remains unchanged.

Keywords

research misconduct; fabrication; falsification; plagiarism; definition; sexual harassment; sabotage; statistics

1. Introduction

On December 6, 2000, following nearly a decade of debate among academic scientists and leaders of various research agencies, the US Office of Science and Technology Policy (OSTP) adopted a definition research misconduct as “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results... misconduct does not include honest error of differences of opinion (Office and Science and Technology Policy 2000: 76262).” The definition, which, applies to all US federal agencies that conduct or sponsor research, focused on three types of misbehavior—fabrication, falsification, and plagiarism (FFP), and eliminated the category “other serious deviations,” which had been used by the National Institutes of Health (NIH) and other agencies (Resnik 2003). OSTP decided to not include the “other serious deviations” category in the definition of misconduct because it judged it to be vague, all-encompassing, and difficult to enforce; and because investigating and adjudicating cases of other serious deviations in science

would draw resources away from what most scientists considered to be more serious ethical problems in research, i.e. FFP (Steneck 1999, Dooley and Kerch 2000, Resnik 2003). Federal agencies, such as the NIH and National Science Foundation (NSF), have incorporated the OSTP definition of misconduct into their policies and procedures, which academic institutions seeking research funding from these agencies are required to follow.¹

While there is widespread agreement that FFP should be included in the definition of research misconduct, some have argued that the definition should be expanded to include other types of misbehavior. In this commentary, I will argue that the federal definition of misconduct should not be expanded at this time, although scientific organizations, such as professional associations, universities, or journals, may have good reasons to include misbehaviors other than FFP in their definitions to promote their goals.

2. Misconduct Other than FFP

2.1 Sexual Harassment

In the early 1990s, the NSF and the Public Health Service (PHS), which funds research supported by the NIH, defined research misconduct as FFP and “other serious deviations” from accepted scientific practices (Buzzelli 1993:584). In 1992, members of the National Academy of Sciences, Engineering, and Medicine (NASEM) Panel on Scientific Responsibility and the Conduct of Research issued a report in which they argued that the “other serious deviations” category should be eliminated from the definition because it is so vague that scientists may have difficulty knowing what constitutes misconduct. The Panel was concerned that vagueness in the definition of misconduct could discourage scientists from using novel or unorthodox research methods, out of fear that they might be charged with misconduct by deviating from standard practices (National Academies of Science, Engineering, and Medicine 1992: 27, Schachman 1993).

NASEM Panel members were also concerned that the definition might be applied to sexual harassment in science. Panel members recognized that sexual harassment qualifies as a serious violation of the norms of science, but they argued that it should be classified as “other misconduct,” not “research misconduct” because sexual harassment is not unique to science and it is covered by existing laws and institutional policies (National Academies of Science, Engineering, and Medicine 1992: 29). However, some scientists argued that sexual harassment should be included in the definition of misconduct because it can cause serious harm to science and often involves abuses of the supervisor-student relationship. Furthermore, federal agencies need a mechanism for denying funding to researchers who have been convicted of sexual harassment (Buzzelli 1993).

The debate about whether research misconduct definitions should cover sexual harassment has reemerged in the last few years following accusations of sexual misconduct against prominent male scientists (Witze 2015, Wadman 2018a, 2018b, Atkin 2018). According to a

¹The commentary focuses on the US federal definition of research misconduct. It is also worth noting that while most of the top research and development (R &D) funding nations include FFP in their definitions of research misconduct, many also include other categories, such as unethical authorship (54.6%), unethical publication practices (36.4%), failing to report a significant conflict of interest (34.6%), and unethical peer review (31.8%) (Resnik et al. 2015b).

recent report by the NASEM (2018), sexual harassment is a serious problem in science that can cause significant psychological harm, undermine scientific careers, and reduce participation of women in science. In an editorial published in *Nature*, Marín-Spiotta (2018) argues that sexual harassment should be included in the definition of research misconduct to alert researchers to the seriousness of the problem and help prevent it. Last year, the US Geophysical Union (USGU) (2017) decided to include harassment, bullying, and coercive manipulation in its definition of research misconduct to signal the organization's commitment to stopping sexual and other forms of harassment. Recently, the American Association for the Advancement of Science (AAAS) defined gender and sexual based harassment as a type of professional misconduct. AAAS fellows can have their status revoked for breach of professional ethics or misconduct (Hoy 2018). The NSF and NIH recently strengthened their policies concerning sexual harassment in funded research (Witze 2018, Mervis and Kaiser 2018).

2.2 Sabotage

The NASEM Panel also addressed the issue of sabotaging someone's research project in its 1992 report. The Panel argued that sabotage should not be included in the definition of misconduct because it is not unique to the research process and it is (or should be) covered by existing laws or institutional policies (National Academies of Science, Engineering, and Medicine 1992). However, some cases of research sabotage are not adequately covered by existing laws or policies but constitute serious threats to the integrity of science. In 2009, Vipul Brighu, a postdoctoral student at the University of Michigan at Ann Arbor, admitted to sabotaging Heather Ames' research project by switching lids and cell cultures and contaminating them with ethyl alcohol. He pled guilty to destruction of property and was ordered to pay over \$30,000 in restitution and fines (Rasmussen 2014). The university found that he committed research misconduct and the Office Research Integrity (ORI) concurred. As punishment, ORI debarred Brighu from receiving federal funds for a period of three years. ORI determined that Brighu's behavior constituted a type of data falsification because he had improperly changed or manipulated Ames' data (Department of Health and Humans Services 2011). However, one might argue that tampering with research does not fit the definition of research misconduct because data falsification is meant to apply to falsifying one's own data, not someone else's (Rasmussen 2014). An implication of this case is that the federal definition of research misconduct may need to be revised, if one considers sabotage to constitute a serious breach of ethics on a par with FFP.

2.3 Deceptive Uses of Statistics

Deceptive use of statistics is third type of misbehavior the NASEM Panel addressed in its 1992 report. Many research projects in fields such as genomics, proteomics, epidemiology, neuroscience, systems biology, geology, ecology, and astronomy involve complex statistical analyses of 100,000 or more of data points (i.e. "big data"). Researchers could deceptively manipulate data to achieve a desired result by, for example, choosing a statistical test or model that presents their hypothesis in the most favorable light or misstating or obscuring assumptions and interpretive frameworks (Resnik et al. 2017). Some of these practices could be viewed as highly dishonest and unethical even if they do not fit neatly into the categories of data fabrication or falsification (Gardenier and Resnik 2002).

For example, in 2006 Duke University Medical Center (DUMC) faculty members Anil Potti, Joseph Nevins, and collaborators published a paper in *Nature Medicine* describing a statistical model for predicting the response to chemotherapy from the genomic signatures of tumors (Potti et al. 2006). The model was based on large genomic and clinical datasets. A few months later, several statisticians published a commentary on the paper in which they claimed the results were not reproducible and that the methods were poorly executed (Coombes et al. 2007). They also asked Potti and Nevins to provide them with the computer codes from programs used to analyze the data, which had not been shared publicly, so they could better understand problems they detected with the research (Resnik 2018). After the commentary was published, DUMC temporarily halted clinical trials that used the model to guide cancer treatment but then restarted them after an investigation found no problems with the research design or methodology. In 2008, Bradford Perez, a medical student working with Potti, discovered significant problems with the software used to develop the model and learned that it had not been independently validated. In 2009, DUMC stopped the trials again and launched a misconduct investigation against Potti after the *Cancer Letter* reported that Potti had falsely claimed he was a Rhodes Scholar on his curriculum vitae and grant applications (Resnik 2018). In 2012, DUMC found that Potti had fabricated and falsified data used to develop the model and ORI agreed with this finding (Office of Research Integrity 2015).

In thinking about this case, it is important to note that this research involved deceptive use of statistics in addition to data fabrication and falsification. Indeed, the research would have been ethically questionable even if Potti had not fabricated or falsified data. The Institute of Medicine (IOM) specifically referred to this case in its 2012 report on the use of genomics and proteomics to test for diseases and predict responses to drugs. The IOM report chastised DUMC researchers for failing to detect problems with research data and computational methods, not making computer codes and data publicly available, and placing cancer patients in clinical trials at risk (Institute of Medicine 2012).

The NASEM Panel argued that deceptive use of statistics should be classified as a “questionable research practice” but not misconduct (National Academies of Science, Engineering, and Medicine 1992:28). Questionable research practices are misbehaviors that are detrimental to science but that should be viewed as misconduct because scientists do not agree about the seriousness of these practices or how to define them. Other questionable research practices include inappropriate authorship, poor record-keeping, inadequate supervision of subordinates, and refusing to share data or materials (National Academies of Science, Engineering, and Medicine 1992). The NASEM Panel acknowledged that the line between questionable research practices and misconduct can be blurry at times. For example, non-transparent removal of data outliers could be viewed as falsification, depending on the circumstances (National Academies of Science, Engineering, and Medicine 1992:28; Shamoo and Resnik 2015).

2.4 Failure to Disclose a Significant Conflict of Interest

The NASEM report did not discuss failure to disclose a significant conflict of interest (COI) in research but this type of misbehavior is currently a matter of serious concern and has been

for several decades (Shamoo and Resnik 2015). Since the mid-1980s, funding agencies, academic institutions, and scientific journals have adopted policies mandating disclosure of COIs. The goals of these policies are to promote transparency and objectivity in science and assure the public of the trustworthiness of the research enterprise (Shamoo and Resnik 2015). Although all policies include some disclosure requirements, very few have enforcement procedures or penalties for non-compliance.

On September 8, 2018, the *New York Times* reported that José Baselga, the chief medical officer at Memorial Sloan Kettering Cancer Center, failed to disclose millions of dollars he received from pharmaceutical and health care companies in dozens of articles submitted for publication in top medical journals, including the *New England Journal of Medicine* and *The Lancet* (Ornstein and Thomas 2018). This revelation created outrage among ethicists, researchers, and members of the public. In a commentary published in the *Journal of the American Medical Association*, Jeffrey Botkin discussed this problem and argued that failure to disclose a significant COI should be treated research misconduct because it amounts to falsifying the research record, since it creates a false picture of the research environment to funders, researcher institutions, and journal reviewers and readers (Botkin 2018). Botkin further argued that while institutions, funders, and journals already have COI policies that mandate disclosure, these policies are rarely enforced against non-compliant individuals, so stronger enforcement mechanisms are needed (Botkin 2018).

Botkin's suggestion that not disclosing a significant COI should be viewed as a type of falsification is creative it does not fit the federal definition of falsification. The OSTP policy defines falsification as: "Falsification 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 (Office and Science and Technology Policy 2000: 76262)." Falsification involves either manipulating research materials, equipment, processes or changing or omitting data. While not disclosing a COI may inaccurately represent the research ², 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.

3. Revising the Federal Definition of Research Misconduct?

So, the idea that research misconduct should be equated with FFP is not sacrosanct, since federal agencies at one time had a more expansive definition of misconduct. But should the current federal definition of misconduct be revised to include sexual harassment or other misbehaviors?

To address this question, it is important to understand the purpose of the federal definition of research misconduct. The main purpose of the federal definition is to establish legally enforceable standards for the ethical conduct of research supported by federal agencies (Office and Science and Technology Policy 2000). The federal definition of research

²It is worth noting that other ethically questionable research practices, such as not naming a significant contributor as an author, may also inaccurately represent research.

misconduct falls into an area of law known as administrative law because it pertains to how federal agencies administer their rules and regulations (Resnik 2003). Agency findings of misconduct can lead to administrative actions (i.e. punishments), such as prohibitions of receipt of federal funds for grants or contracts. These actions are governed by legal standards of due process. To comply with these standards, the misconduct definition must be clearly stated so that a reasonable person would know whether they have or have not committed misconduct and how to defend themselves against an accusation. (Resnik 2003). The definition must also be publicized to put scientists on notice concerning behavioral standards. Agencies must also establish policies and procedures for investigating and adjudicating misconduct that comply with due process requirements and protect whistleblowers. The federal definition of misconduct also serves other purposes, such as promoting integrity in research generally, but its main purpose relates to enforcement of laws.

With this legal framework in mind, let's consider four conditions for including a behavior in the federal definition of misconduct. These conditions, which have been discussed and defended elsewhere (see National Academies of Science, Engineering, and Medicine 1992, Resnik 2003), are criteria for defining legally enforceable ethical standards for the conduct of research.

4. Conditions for Including a Behavior in the Federal Definition of Misconduct

4.1 The behavior is widely regarded as highly unethical

To understand the first condition, we can view behavior in science as falling on a normative scale, with ethical conduct and misconduct on opposite ends. Somewhere in the middle are behaviors that are ethically dubious or controversial, i.e. questionable research practices (National Academies of Science, Engineering, and Medicine 1992, Shamoo and Resnik 2015). Nearly all definitions of research misconduct include FFP, because most scientists regard these behaviors as highly unethical. Most scientists would probably also regard sexual harassment, sabotage, deceptive use of statistics, and failure to disclose a significant COI as highly unethical (National Academy of Sciences 2002, Shamoo and Resnik 2015, Botkin 2018).

4.2 The behavior significantly threatens the integrity of science

In thinking about the second condition, we can equate scientific integrity with adherence to norms that directly or indirectly promote the goals of science, i.e. the development of knowledge and the acquisition of true beliefs about the natural world (Shamoo and Resnik 2015). Data fabrication and falsification directly threaten the goals of science because these behaviors lead to the publication of erroneous results, which undermines the search for knowledge and truth. Although plagiarism does not involve the publication of erroneous results, it indirectly threatens the goals of science because it is a form of intellectual theft that negatively impacts the social structure of science by undermining trust among researchers, creating hostility and resentment, and interfering with career advancement (Shamoo and Resnik 2015). Likewise, sexual harassment also does not involve the

publication of erroneous results, but it also has far-reaching negative impacts on the social structure of science (National Academies of Science, Engineering, and Medicine 2018).³ Deceptive use of statistics directly threatens the integrity of science by leading to the publication of erroneous or biased research. Sabotage may also threaten the integrity of science by undermining the social structure of science; however, it is not known how common sabotage is in science, because most surveys of misbehavior in science have focused on FFP and other unethical practices and not sabotage (Fanelli 2009). So, sabotage may threaten the integrity of science but not pose a significant threat because we do not know at this time whether it is common enough to pose a significant threat. Finally, not disclosing a significant COI can threaten the integrity of science by preventing researchers and other concerned parties from learning about financial and other relationships that may impact objectivity of the data, results, and interpretations (Shamoo and Resnik 2015, Botkin 2018). Information about COIs is often useful for evaluating the objectivity, quality, and credibility of research (Resnik and Elliott 2013).

4.3 The behavior can be clearly defined

The third condition is important for providing scientists with appropriate guidance, deterring misconduct, and legally enforcing ethical standards. Vagueness in the definition of misconduct might fail to discourage scientists from engaging in misconduct, since scientists cannot easily avoid doing something if they do not know how it is defined. As noted earlier, the NASEM Panel was concerned that vagueness could also have a chilling effect on research by discouraging scientists from using novel methods or practices if they fear that their research activities could be construed as misconduct (National Academies of Science, Engineering, and Medicine 1992). Since novelty is important for developing new theories, concepts, and methodologies, vague definitions of misconduct could hamper scientific progress (Resnik et al. 2017). Clarity is also important for enforcement, since it is unfair to hold scientists accountable for misbehavior if they do not understand how to avoid it (Resnik 2003). Also, if a definition is vague it may apply to such a wide range of behavior that enforcement becomes impractical or impossible.

Fabrication, falsification, and plagiarism meet this third condition because they are clearly defined in federal policies (Office of Science and Technology Policy 2000). Sexual harassment, which has a clear definition in the law and institutional policies, also meets the third condition. Likewise, sabotage probably also meets the third condition because it can be defined as deliberately interfering with someone's research to prevent them achieving their goals. One problem with including deceptive use of statistics in the definition of misconduct is that the concept is so vague that it might deter scientists from using novel statistical methods, tests, or models (Resnik et al. 2017). Deceptive use of statistics should be included in the definition of misconduct only if it can be clearly defined, which may be difficult to do, given the evolving nature of statistical practice and the complexity of statistical methods, tests, and models. More analysis of deceptive use of statistics is needed before we can say whether it meets this third condition. It is likely to be difficult to define a "significant COI"

³There are many misbehaviors that can negatively impact the social structure of science, including racism and bullying, but I will not discuss them here.

since many factors affect significance, such as the type of relationship at issue (e.g. financial or professional), the nature of the relationship (e.g. consulting, receiving funds for research) and the amount of money or stock involved (for financial relationships). Moreover, the definitions of COIs used by funding agencies, institutions, and journals differ substantially in content and form (Shamoo and Resnik 2015, Resnik et al. 2016, Resnik et al. 2017).

4.4 Existing Methods of Enforcement or Deterrence are Inadequate

The fourth condition also relates to practical considerations, since there is no need to waste resources enforcing or deterring standards of behavior if existing methods of enforcement or deterrence are adequate to the task. One might argue that there is no need to include sexual harassment in the definition of research misconduct, since existing laws and institutional policies already prohibit and deter this behavior. Without a doubt, sexual harassment is misconduct, but one might argue that it is not research misconduct (National Academies of Science, Engineering, and Medicine 1992). However, one might object to this argument by pointing out the sexual harassment sometimes occurs in situations that are not clearly governed by sexual harassment laws or policies, such as research conferences, and that existing sexual harassment laws are not adequately enforced. One might argue that existing laws do not adequately deter or prohibit research sabotage, since only some forms of sabotage, such as those involving destruction of property, are illegal. Switching labels on petri dishes would be a form of sabotage that would not involve destruction of property. Likewise, existing laws do not adequately deter deceptive use of statistics, since only deceptions involving fabrication, falsification, or fraud are illegal (Shamoo and Resnik 2015). Although Botkin correctly points out that existing COI policies do not adequately deter non-compliance, these policies could be modified to include stronger enforcement mechanisms. For example, journals could retract articles for non-compliance with their COI policies or refuse to accept future submissions from researchers who fail to disclose significant COIs. Funding agencies could debar investigators for non-compliance with COI policies.

4.5 Summary: Applying the Four Conditions

While fabrication, falsification, and plagiarism clearly meet all four conditions for including a type of misbehavior in the federal definition of research misconduct (Shamoo and Resnik 2015), it is not obvious that the four other misbehaviors discussed above meet these conditions. Sexual harassment meets conditions 1, 2, and 3, but probably not 4; deceptive use of statistics meets 1, 2, and 4, but probably not 3; sabotage meets conditions 1, 3, and 4, but probably not 2; and failure to disclose a significant COI meets conditions 1 and 2 but not 3 and 4. So, one might argue that the federal definition should not be expanded to include these four types of misbehavior, at least until we have a better understanding of how sexual harassment laws are enforced in science, the impact of sabotage on scientific research, whether deceptive use of statistics and failure to disclose a significant COI can be clearly defined, and whether funding agencies, institutions, and journals are likely to strengthen their COI policies to better deter non-compliance (See Table 1).

5. Other Uses of Research Misconduct Definitions

While the US federal definition of research misconduct plays an important role in promoting integrity in science and deterring unethical behavior, it is not the only definition that performs this function. Professional associations, universities, and scientific journals have their own definitions of research misconduct, which may serve purposes different from those served by the federal definition. Professional associations often adopt ethics codes not only to establish norms for behavior but also to assure the public that their members are honorable and trustworthy. A professional association may be more interested in taking a public stance on an issue or establishing a normative ideal than in legally enforcing a behavioral norm (Bayles 1988). Indeed, professional associations have little power to punish wrongdoers, other than to suspending or revoking membership in the association, and they rarely discipline members. As noted above, the USGU and AAAS have changed their definitions of misconduct to include sexual harassment and are planning to act against wrongdoers. Other professional societies may decide to do take similar measures to address sexual harassment problems. Although professional associations may decide to discipline members who commit misconduct, these actions do not have the same types of legal consequences that result from a misconduct finding from a federal agency, and they do not need to meet the same standards of legal due process that apply to state actors.

Universities may decide to expand their definitions of misconduct beyond FFP to establish standards for behavior in the academic setting, protect their reputations, maintain good relations with sponsors and collaborating institutions, and have a legal basis for taking actions (such as formal reprimand, suspension of enrollment, or termination of employment) against faculty members, administrators, staff, or students who violate the standards. Over half (59%) of the top US research institutions include misbehaviors other than FFP in their misconduct definitions, such as other serious deviations (45.4%), significant or material violations of research regulations (23%), misuse of confidential information (15.8), interfering with a misconduct investigation (14.8%), and unethical authorship (14.2%) (Resnik et al. 2015a). When university definitions of research misconduct are used to enforce legally enforceable standards of conduct, they must be clearly defined. Some misbehaviors included in university definitions, such as “serious deviations” and “unethical authorship” may not meet this condition.

Professional journals may also decide to include misbehaviors other than FFP in their definitions of misconduct to ensure the integrity of the research record and protect their reputations for publishing only high quality, ethical science (Resnik et al. 2009). Journals may be more concerned about misbehaviors related to publications issues (such as FFP or not disclosing a significant conflict of interest) than those pertaining to problems in the research environment (such as harassment or sabotage), because their focus is on scientific publication. The Committee on Publication Ethics (1999: 46), which provides guidance for journals, editors, reviewers, and authors, defines misconduct as very generally as “intention to cause others to regard as true that which is not true.” This definition may apply not only to FFP but also to deceptive use of statistics or failure to disclose a significant COI. Journals usually refer allegations of misconduct to the authors’ research institutions for resolution (Committee on Publication Ethics 1999, Resnik et al. 2015b). Journals have several options

for enforcing their ethical standards, such as retracting articles affected by misconduct, publishing editorial expressions of concern while investigations are ongoing, or prohibiting authors who violate their standards from publishing in their journal in the future.

Private research sponsors may decide to adopt definitions of misconduct to promote public trust in their organization and responsible management of funds. The Wellcome Trust, which funds over \$1billion worth of scientific research around the globe each year, defines research misconduct as “behaviour or actions that fall short of the standards of ethics, research and scholarship required to ensure that the integrity of research is upheld (Wellcome Trust 2018).” Since this definition uses the vague term “behaviour that falls short of the standards of ethics,” it may be difficult to legally enforce.

6. Conclusion

While the arguments for revising the federal definition 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. Since these other organizations play an important role in promoting integrity in science and deterring unethical behavior, they may consider adopting definitions of misconduct that extend beyond FFP. Debates about the definition of research misconduct are a normal and healthy part of broader discussions about integrity in science and how best to promote it. These debates should continue even if the federal definition of misconduct remains unchanged.

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Table 1:

Conditions for Including a Behavior in the Federal Definition of Research Misconduct

	Fabrication	Falsification	Plagiarism	Sexual Harassment	Sabotage	Deceptive Use of Statistics	Failure to Disclose a Significant COI
Widely Regarded as Highly Unethical	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Significant Threat to Research Integrity	Yes	Yes	Yes	Yes	Probably not, but more information is needed	Yes	Yes
Can be Clearly Defined	Yes	Yes	Yes	Yes	Yes	Probably not, but more analysis is needed	Probably not
Other Methods of Enforcement or Deterrence Inadequate	Yes	Yes	Yes	Probably not, but more information is needed	Yes	Yes	No, if current COI policies are better enforced