

POLICING RESEARCH MISCONDUCT

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I. INTRODUCTION

Testifying before the Senate Subcommittee on Health and Scientific Research in October 1979, Doctor Michael Hensley of the Food and Drug Administration’s (“FDA”) Division of Scientific Investigations told the assembled members of Congress the story of Doctor 31.¹ Doctor 31 had served as an investigator for clinical trials of drugs for a variety of prominent pharmaceutical firms, but it had been discovered that the data used in these studies was “entirely fabricated.”² When confronted by FDA inspectors, Doctor 31 asserted his innocence.³ According to Hensley:

Doctor 31 characterized himself as a compulsive worker. He stated that he really had done the studies but he just had so much to do that he felt that he had to take the work with him on a picnic and had the data in a rowboat with him. And the rowboat allegedly capsized. The data went to the bottom in a metal box and was not retrievable.⁴

Further investigation by FDA revealed, unsurprisingly, that the rowboat incident never occurred.⁵ It also revealed that Doctor 31 was not a doctor at all—his academic credentials, like his data, had been fabricated.⁶ The story of Doctor 31 may be

¹ *Preclinical and Clinical Testing by the Pharmaceutical Industry, 1979: Hearing Before the Subcomm. on Health & Scientific Research of the Comm. on Labor & Human Res., 96th Cong. 23 (1979) (statement of Michael J. Hensley, M.D., Division of Scientific Investigations, Food and Drug Administration).*

² *Id.*

³ *Id.*

⁴ *Id.*

⁵ *Id.* at 23–24.

⁶ *Id.* at 24–25.

humorous, but it is also alarming: this individual was entrusted with real clinical patients.

The fact that Doctor 31's research was not scrutinized earlier or more thoroughly in part reflects an historical trend. Science has long occupied a "privileged status' in American society[,] not exactly above the law, but in many ways outside it."⁷ Even as we have vigorously debated whether scientists should engage in certain types of research (e.g. atomic weapons or human cloning) and how best to protect human research subjects, we have assumed that scientists are essentially honest—even noble—individuals who can be trusted to conduct their research carefully and with integrity.⁸ Indeed, as one commentator has observed, "even the archetypal evil scientist, the 'mad scientist' of horror film and literary clichedom, was always motivated by the search for truth."⁹ H.G. Wells's Dr. Moreau is an unsettling character, to be sure, but we can rest assured that he never falsified an entry in his experimental logs.¹⁰

Evidence suggests, however, that our faith in scientists may be misplaced. Even if we take as true the suspect assertion that research scientists are less motivated by pecuniary gain than other people, there remain a variety of potential motives for fraud. These include the "social pressure to make important discoveries,"¹¹ the scientist's desire to be "elevate[d] . . . in the eyes of his peers,"¹² and professional pressure to publish articles in prominent journals and acquire grant funding, particularly for faculty still seeking tenure, but also afterwards.¹³ Though reliable statistics on the prevalence of research misconduct are notoriously elusive, one recent meta-analysis of studies asking scientists about their experiences of misconduct found that around two percent of scientists admitted to having themselves "fabricated, falsified or modified data or results at least once . . . and up to one third admitted a variety of other

⁷ Glenn Harlan Reynolds, "Thank God for the Lawyers": *Some Thoughts on the (Mis)Regulation of Scientific Misconduct*, 66 TENN. L. REV. 801, 802 (1999).

⁸ *Id.*

⁹ *Id.*

¹⁰ H.G. WELLS, *THE ISLAND OF DOCTOR MOREAU* (Steven Palmé ed., Dover Publ'ns, Inc. 1996) (1896).

¹¹ Daniel Goldberg, *Research Fraud: A Sui Generis Problem Demands a Sui Generis Solution (Plus a Little Due Process)*, 20 T.M. COOLEY L. REV. 47, 50 (2003).

¹² *Id.*

¹³ See discussion *infra* Part III.

questionable research practices.”¹⁴ The two-percent figure is in line with the result of routine data audits conducted by FDA between 1977 and 1990, which found deficiencies and flaws in 10–20 percent of studies, but which led to findings of serious misconduct in about two percent of cases.¹⁵ Another more recent study reviewed all 2,047 retracted biomedical and life science articles in the PubMed database and found evidence of widespread misconduct.¹⁶ The study found that fraud or suspected fraud accounted for 43.4 percent of all retractions, with plagiarism accounting for an additional 9.8 percent.¹⁷

Although two percent may not sound like pervasive fraud, the amount of money spent on studies compromised by misconduct mounts quickly. If research misconduct resulted in the loss of two percent of the \$136 billion that government, industry, and non-profit sources reportedly invested in health-related R&D in 2011,¹⁸ that would mean a loss of around \$2.7 billion, or more than the National Science Foundation’s (“NSF”) entire annual contribution to health research.¹⁹ Regardless of the prevalence of fraud or the amount of money involved, any misconduct in scientific research presents a serious problem.²⁰ It not only undermines scientific progress and trust in the scientific establishment, but wastes scarce public and private research funding, and can ultimately endanger the public if FDA relies on a study to approve a clinical trial or a drug marketing application.²¹ Detecting and preventing misconduct, a “low

¹⁴ See Daniele Fanelli, *How Many Scientists Fabricate and Falsify Research?: A Systematic Review and Meta-Analysis of Survey Data*, 4(5) PLOS ONE e5738, at 8 (May 29, 2009), available at <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0005738> (“[O]ther questionable research practices include[e] ‘dropping data points based on a gut feeling’ and ‘changing the design, methodology or results of a study in response to pressures from a funding source.’”).

¹⁵ *Id.* at 2.

¹⁶ Ferric C. Fang et al., *Misconduct Accounts for the Majority of Retracted Scientific Publications*, 109 PROC. NAT’L ACAD. SCI. 17028, 17028 (2012).

¹⁷ *Id.*

¹⁸ RESEARCH!AMERICA, 2011 U.S. INVESTMENT IN HEALTH RESEARCH 3 (2011), <http://www.researchamerica.org/uploads/healthdollar11.pdf>.

¹⁹ NSF’s expenditures on health research in 2011 totaled only \$2.358 million according to the Research!America report. *Id.*

²⁰ Rebecca Ann Lind, *Evaluating Research Misconduct Policies at Major Research Universities: A Pilot Study*, 12 ACCOUNTABILITY IN RESEARCH 241, 242 (2005).

²¹ Donald S. Kornfeld, *Perspective: Research Misconduct: The Search for a Remedy*, 78 ACAD. MED. 877, 877 (2012).

prevalence but high impact phenomenon,”²² is a vital project.

The current regime for investigating allegations of research misconduct in the United States does not provide a mechanism to accurately measure, let alone redress, the full scope of misconduct. The current system fails on five key dimensions. First, the existing rules about what research institutions must report to regulators limits regulators’ (and the public’s) ability to fully understand the character and extent of the research misconduct problem.²³ Second, the groups and individuals presently assigned as the primary investigators of misconduct frequently lack relevant investigational experience and expertise, and are frequently subject to conflicts of interest arising from personal and professional relationships with respondents.²⁴ Third, the existing regulatory regime delegates significant authority to research institutions to set their own policies and procedures and to conduct their own investigations without sufficient oversight or emphasis on uniform adoption of best practices.²⁵ Fourth, current confidentiality rules often prevent the individuals and institutions that review allegations of misconduct from having access to important and relevant information about past allegations against, and settlements with, respondents.²⁶ Finally, the present structure allows relevant stakeholders to treat cases of confirmed misconduct as essentially isolated incidents, potentially leading to the continued corruption of the scientific record.²⁷

This article considers a variety of regulatory changes aimed at generating more reliable data to measure the scope of the misconduct problem and improving enforcement when misconduct occurs.²⁸ Some of the proposed changes are low-cost, high-impact changes that could be implemented with

²² Lind, *supra* note 20, at 241–42.

²³ See discussion *infra* Part III.A.

²⁴ See discussion *infra* Part III.B.

²⁵ See discussion *infra* Part III.C.

²⁶ See discussion *infra* Part III.D.

²⁷ See discussion *infra* Part III.E.

²⁸ This article focuses on possible improvements to the flawed regulatory regime, but this emphasis by no means denies the important role played by private actors in preventing, detecting, and punishing research misconduct. Research institutions and scientific journals, in particular, have both the ability and the motivation to be key contributors in controlling misconduct. While a full discussion of the possibilities and limitations of private responses is beyond this article’s scope, these issues are discussed at various points herein. See discussion *infra* Part III.C.

comparative ease, such as expanded reporting requirements, modified confidentiality rules, greater federal guidance in designing institutional policies for funded research, increased use of third-party data audits, and increased federal auditing of cases not pursued by research institutions.²⁹ Other proposed changes would represent more radical departures from the status quo. The costs of such changes might only be justified if additional evidence demonstrates that the problem of research misconduct is especially grave.³⁰ These more fundamental changes, identified in the interest of laying a foundation for future discussion rather than as current prescriptions, include expanding the government's role in investigating alleged misconduct, shifting the burden of proof in research misconduct cases onto respondents, and imposing greater vicarious penalties on research institutions for the misconduct of their members.³¹

This article adopts the definition of research misconduct used in the Federal Policy on Research Misconduct (the "Federal Policy"), the same definition used by federal agencies that conduct or support research using federal funds. The policy defines research misconduct as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results."³² This definition, referred to as FFP (for its component parts), does not include honest error or differences of opinion.³³ FFP is admittedly a narrow definition of misconduct and one that does not reach some clearly inappropriate conduct, including many human-subjects violations.³⁴ While much of the conduct proscribed by the Federal Policy for the Protection of Human Subjects (the "Common Rule")³⁵ could be described as "research misconduct" in a general sense, this article intentionally does not attempt to address the unique issues presented by the human-subjects rules, which have

²⁹ See discussion *infra* Part IV.

³⁰ See discussion *infra* Part V.

³¹ See discussion *infra* Part V.

³² Federal Policy on Research Misconduct, 65 Fed. Reg. 76,260, 76,262 (Dec. 6, 2000).

³³ *Id.*

³⁴ See Melissa L. Markey, *Scientific Misconduct in Research*, 1 J. HEALTH & LIFE SCI. L. 63, 71–73 (2007) (providing a detailed discussion of the scope of research misconduct as expressed in the FFP definition, contrasted against the broader concept of "research integrity").

³⁵ See *Federal Policy for the Protection of Human Subjects ("The Common Rule")*, U.S. DEP'T OF HEALTH & HUMAN SERVS., <http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html> (last visited Jan. 31, 2015).

their own complex history and application and raise related but distinct problems. Neither does this article purport to address the broad category of scientific misconduct which, while perhaps falling short of the FFP definition, nonetheless has the effect of corrupting or muddying the scientific record.

The structure of this article proceeds as follows: Part II provides an overview of the current federal regulatory approach to research misconduct, focusing in particular on the Federal Policy on Research Misconduct and the FDA's Application Integrity Policy. Part III describes the shortcomings of this approach, and Parts IV and V propose and discuss a number of possible reforms.

II. AN OVERVIEW OF CURRENT FEDERAL POLICY

Research misconduct is regulated through four principal public and private mechanisms.³⁶ First, federal agencies are responsible for policing misconduct related to federally funded research by implementing the uniform Federal Policy.³⁷ While all agencies that sponsor or conduct research must adhere to and implement the Federal Policy, this article focuses primarily on the Office of Research Integrity ("ORI") within the Department of Health and Human Services ("HHS"), because its jurisdiction over the National Institutes of Health ("NIH") means it oversees the overwhelming majority of federally funded research.³⁸ Second, FDA has a major role in overseeing both basic and clinical research that is used to support regulatory submissions.³⁹ This role encompasses both routine inspections and investigation and enforcement where misconduct is suspected.⁴⁰ Third, private entities that either sponsor or conduct research engage in self-regulation to prevent, investigate, and punish misconduct.⁴¹

³⁶ See generally Bratislav Stankovic, Comment, *Pulp Fiction: Reflections on Scientific Misconduct*, 2004 WIS. L. REV. 975, 984–88 (2004) (discussing different enforcement methods for research misconduct and cases which resulted from them).

³⁷ Federal Policy on Research Misconduct, 65 Fed. Reg. at 76,260.

³⁸ See Chris B. Pascal, *The Office of Research Integrity: Experience and Authorities*, 35 HOFSTRA L. REV. 795, 795 (2006) (discussing ORI jurisdiction over federally funded health research).

³⁹ Markey, *supra* note 34, at 68.

⁴⁰ *Id.* at 63, 68, 73, 79–80.

⁴¹ See Federal Policy on Research Misconduct, 65 Fed. Reg. at 76,263 (explaining the responsibilities of institutions and their role in investigations).

Finally, research institutions are subject to applicable state laws.⁴² Because the scope of each of these systems is limited, we rely on the combination of all four to achieve the overall goals of preventing, discovering, and punishing misconduct.⁴³ This article focuses primarily on the Federal Policy, though it necessarily touches to some extent upon some of the ways that this policy either delegates to or overlaps with the other mechanisms.

A. *The Federal Policy on
Research Misconduct*

1. Introduction to the Federal Policy

In December of 2000 the Office of Science and Technology Policy (“OSTP”) within the Executive Office of the President issued a government-wide policy on research misconduct through notice-and-comment rulemaking.⁴⁴ The policy, which covers all research either performed or sponsored by U.S. government agencies, was the culmination of over a decade of debate about the proper role for the federal government in defining and policing research misconduct.⁴⁵ Each federal agency is required to implement the policy, and to “strive for the highest level of uniformity possible,” although the actual “rights, privileges, benefits, or obligations” created by the policy derive from each agency’s specific implementation.⁴⁶ In practice, the policy’s most important enforcer is ORI, which implements the policy for the large portion of federal research funds administered by NIH. In addition to funded research, ORI has jurisdiction over misconduct in applications for such funding and in activities related to funded research, including research training, tissue banking, databases, and the dissemination of research results.⁴⁷

2. Mechanics of the Federal Policy

The Federal Policy and the ORI regulations implementing it

⁴² *Id.* at 76,260.

⁴³ *See id.* at 76,263 (discussing the responsibilities of different agencies and institutions in preventing and reporting misconduct).

⁴⁴ *Id.* at 76,260.

⁴⁵ Rebecca Dresser, *Defining Research Misconduct: Will We Know It When We See It?* 31 HASTINGS CENTER 31, 32 (2001).

⁴⁶ Federal Policy on Research Misconduct, 65 Fed. Reg. at 76,262.

⁴⁷ Markey, *supra* note 34, at 73.

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have three main components.⁴⁸ First, they define research misconduct.⁴⁹ Second, they articulate the standard of proof for a finding of misconduct.⁵⁰ Third, they set forth the procedures and structures necessary to respond to an allegation of misconduct.⁵¹

a. Defining Misconduct

The Federal policy defines research misconduct as fabrication, falsification, and plagiarism.⁵² “Fabrication is making up data or results and recording or reporting them.”⁵³ “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.”⁵⁴ “Plagiarism is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.”⁵⁵ As others have observed, these three forms of misconduct reflect a kind of hierarchy of blameworthiness.⁵⁶

Fabrication is the greatest sin because it is the most divorced from the imagined purposes of science. The individual who deliberately reports “experiments that were never conducted, observations that were never performed, [or] calculations that were never made” has committed the “most blatant and most blameworthy” form of research misconduct.⁵⁷ Fabricated records and reports by their nature do nothing to advance science, but they can and do mislead others, waste resources, and undermine public trust.⁵⁸

⁴⁸ See Federal Policy on Research Misconduct, 65 Fed. Reg. at 76,262–64.

⁴⁹ Research Misconduct, 42 C.F.R. § 93.103 (2014); see also Federal Policy on Research Misconduct, 65 Fed. Reg. at 76,262.

⁵⁰ Federal Policy on Research Misconduct, 65 Fed. Reg. at 76,262.

⁵¹ *Id.* at 76,263.

⁵² The Federal policy’s definition of research misconduct and the terms used in that definition are formally adopted for purposes of ORI investigations in Research Misconduct. 42 C.F.R. § 93.103.

⁵³ Federal Policy on Research Misconduct, 65 Fed. Reg. at 76,262.

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ See, e.g., Nisan A. Steinberg, *Regulation of Scientific Misconduct in Federally Funded Research*, 10 S. CAL. INTERDISC. L.J. 39, 47–55 (2000).

⁵⁷ Dan L. Burk, *Research Misconduct: Deviance, Due Process, and the Disestablishment of Science*, 3 GEO. MASON INDEP. L. REV. 305, 311 (1995) (quoting Harriet Zuckerman, *Deviant Behavior and Social Control*, in SCI. IN DEVIANCE AND SOC. CHANGE 87, 126–27 (Edward Sagarin, ed. 1977)).

⁵⁸ ORG. FOR ECONO. CO-OPERATION & DEV. GLOBAL SCI. FORUM, BEST PRACTICES FOR ENSURING SCIENTIFIC INTEGRITY AND PREVENTING MISCONDUCT 1

Falsification is less blameworthy than fabrication if only because the underlying experiments and observations are in many cases valid, and the sin of falsification often misrepresents rather than corrupts the scientific record.⁵⁹ While one form of falsification—the selective reporting or “trimming” of data to fit the researcher’s particular hypothesis—is similar to fabrication in its capacity to mislead the public and future researchers, other instances of falsification essentially involve “massaging” otherwise accurately reported data to reach a desired result, which is “arguably less harmful than trimming, because other workers can later recalculate or reinterpret the results using the accurate raw data.”⁶⁰

Plagiarism, the least serious of the officially recognized forms of misconduct, “offends the scientific norms of communism and disinterestedness but it does not ‘corrupt’ the scientific literature with unreliable information.”⁶¹ While the inclusion of plagiarism in the government’s official definition of research misconduct may initially seem odd, if the goal of the policy is to protect the scientific record, there is a valid argument to be made for prohibiting plagiarism under the Federal Policy. This is because it is not necessarily true that the only wrong in a case of plagiarism is “garnering peer recognition without contributing anything original to the scientific canon.”⁶² To the contrary, in thinking about plagiarism in the context of the Federal Policy, we might instead characterize the harm as collecting and expending federal resources without contributing anything original to the scientific canon.⁶³ After all, the Federal Policy on Research Misconduct is ultimately a set of conditions imposed on recipients of federal funds.⁶⁴

When the Federal Policy is viewed in this light, it is interesting that other misconduct that goes to the improper use of resources

(Nov. 2007), <http://www.oecd.org/sti/sci-tech/40188303.pdf> [hereinafter OECD BEST PRACTICES].

⁵⁹ Steinberg, *supra* note 56, at 49.

⁶⁰ *Id.* at 49–50.

⁶¹ *Id.* at 50.

⁶² Burk, *supra* note 57, at 312.

⁶³ See Steinberg, *supra* note 56, at 44–45 (noting that scientists compete for scarce federal funds to conduct research).

⁶⁴ This is useful to keep in mind when comparing the policy’s functions with the role played by the FDA, which is overtly concerned with the reliability of the data, and has no particular regulatory interest in whether resources were wasted in its production. *Cf.* Federal Policy on Research Misconduct, 65 Fed. Reg. at 76,260 (Dec. 6, 2000).

(but not to the corruption of the scientific record) is not similarly prohibited.⁶⁵ Early attempts to articulate a unified federal definition of misconduct did in fact include regulations and proposals to prohibit a broader array of research misconduct. The original 1989 HHS regulation defining misconduct, published in response to a 1985 directive from Congress to develop rules for recipients of Public Health Service (“PHS”) research funds, defined “misconduct in science” as: “[f]abrication, falsification, plagiarism, deception or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research.”⁶⁶

Likewise, the National Science Foundation regulations in 1991 included a provision defining misconduct that encompassed both FFP and retaliation against good-faith whistleblowers.⁶⁷ And, a 1995 proposal by the HHS Commission on Research Integrity would have adopted a particularly broad definition of misconduct: “[s]ignificant misbehavior that improperly appropriates the intellectual property or contributions of others, that intentionally impedes the progress of research, or that risks corrupting the scientific record or compromising the integrity of scientific practices.”⁶⁸

The narrow definition that was finally adopted was the product of a prolonged battle over these broader proposals, in which scientists and their professional organizations fought hard to keep open-ended definitions out.⁶⁹ The final policy reflects the scientists’ success: it prohibits only the most blatant forms of misconduct and plagiarism, which the scientific community has a strong, self-motivated interest in preventing.⁷⁰ The effect is that merely careless or sloppy researchers are very rarely guilty of

⁶⁵ Of course, misuse of federal funds is prohibited under other statutes and regulations, and elaborate rules about proper uses and billing procedures exist under relevant circulars and in grant and other funding agreements. *See* 42 U.S.C. § 3795 (2012); 18 U.S.C. § 666 (2012); Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 78 Fed. Reg. 78,590, 78,598 (Dec. 26, 2013).

⁶⁶ Responsibilities of Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science, 54 Fed. Reg. 32,446 (Aug. 8, 1989).

⁶⁷ Misconduct in Science and Engineering, 56 Fed. Reg. 22,286 (May 14, 1991) (to be codified at 45 C.F.R. pt. 689).

⁶⁸ U.S. DEP’T HEALTH & HUMAN SERVS., INTEGRITY AND MISCONDUCT IN RESEARCH 15 (1995), http://ori.hhs.gov/images/ddblock/report_commission.pdf.

⁶⁹ *See* Dresser, *supra* note 45, at 32.

⁷⁰ *Id.*

misconduct in a formal sense, notwithstanding the damage they may cause to the scientific record and the limited resources they may squander.⁷¹ Meanwhile, research institutions are left to set their own policies for, and conduct their own investigations of, the wide-ranging category of “questionable research practices” and all cases of negligent misconduct.⁷² This deference to self-enforcement, embedded in the federal definition of research misconduct, is a defining trait of the oversight scheme for federally funded research generally, as a closer examination of the Federal Policy makes clear.⁷³

b. Standard of Proof

A finding of research misconduct under the Federal Policy requires three elements: (1) “a significant departure from accepted practices of the relevant research community;” which is (2) “committed intentionally, or knowingly, or recklessly;” and (3) “proven by a preponderance of evidence.”⁷⁴ This standard is generous to regulated parties in at least two ways.

First, it defers to the “accepted practices” of the relevant research community. In response to comments about this language, OSTP clarified that it was:

[I]ntended to make it clear that behavior alleged to involve research misconduct should be assessed in the context of community practices, meaning practices that are generally understood by the community but that may not be in a written form The policy is not intended to ratify those “accepted practices” but rather to indicate that these may vary among different communities.⁷⁵

When considered in combination with the fact that most investigations of alleged misconduct are conducted at the institutional level, this provision is one of several straightforward ways the “unified” federal policy is actually highly fragmented and localized.⁷⁶ The “accepted practices” language also creates a fairly easy way for institutions to reach a negative finding in

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.*

⁷⁴ Federal Policy on Research Misconduct, 65 Fed. Reg. 76,260, 76,262 (Dec. 6, 2000); *see also* Requirements for Findings of Research Misconduct, 42 C.F.R. § 93.104 (2014).

⁷⁵ Federal Policy on Research Misconduct, 65 Fed. Reg. at 76,261.

⁷⁶ *See* Pascal, *supra* note 38, at 797–98 (discussing limitations on ORI jurisdiction).

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borderline cases of misconduct.⁷⁷ In addition to deferring to local norms, the policy also requires a “significant” departure from these norms—another subjective element.

Second, this standard immunizes recipients of federal research funds against allegations of negligent misconduct, “cases in which researchers should have known, but failed to realize, that they were engaged in prohibited behavior.”⁷⁸ To the extent that the Federal Policy can be viewed as (in part) a mechanism to protect substantial government expenditures, it is fairly remarkable that recipients of those funds are expressly protected from repercussions of their negligent conduct.⁷⁹

c. Framework for Investigating Allegations of Research Misconduct

The framework set forth in the Federal Policy should be considered both in terms of the process it affirmatively sets forth and in terms of the substantial elements of that process that it either explicitly or implicitly leaves to the discretion of research institutions. Under the heading “Responsibilities of Federal Agencies and Research Institutions,” the policy begins to describe the process for responding to allegations of misconduct by noting that it is a *joint* venture:

Agencies and research institutions are partners who share responsibility for the research process. Federal agencies have ultimate oversight authority for Federally funded research, but *research institutions bear primary responsibility for prevention and detection of research misconduct* and for the inquiry, investigation, and adjudication of research misconduct alleged to have occurred in association with their own institution.⁸⁰

The process has four basic phases: the allegation, the inquiry, the investigation, and finally adjudication.⁸¹ In executing this process, research institutions must adhere to requirements set forth in the agency-specific regulations implementing the Federal Policy.⁸² For ORI-regulated entities, these obligations are largely laid out in 42 C.F.R Part 93, Subpart C, “Responsibilities of

⁷⁷ See Steinberg, *supra* note 56, at 49–50 (discussing the implications of borderline cases).

⁷⁸ Dresser, *supra* note 45, at 32.

⁷⁹ *Id.*

⁸⁰ Federal Policy on Research Misconduct, 65 Fed. Reg. at 76,263 (emphasis added).

⁸¹ *Id.*

⁸² *Id.* at 76,260.

Institutions.”⁸³ For example, research institutions are required to have written policies and procedures in place that protect the confidentiality of complainants and respondents; provide for a “thorough, competent, objective, and fair response to allegations of research misconduct”; and ensure “[f]ull and continuing cooperation with ORI.”⁸⁴ The regulations dictate the content of some of these policies in detail, while others are left almost wholly to the discretion of the research institutions.⁸⁵

Another key requirement is articulated in 42 C.F.R. § 93.316, which requires research institutions to “carry inquiries and investigations through to completion,” and says that institutions must notify ORI in advance if they intend to close a case for any reason, including a respondent’s admission of guilt or a negotiated settlement with the respondent.⁸⁶

While the Federal Policy places primary responsibility for oversight of federally funded research on research institutions, and ORI’s role is thus usually limited to reviewing the institutional investigations and taking administrative action, there are circumstances under which the federal government will conduct its own inquiry and investigation, and situations where it will choose not to refer allegations it directly receives to the research institutions.⁸⁷ For institutions too small to handle research misconduct investigations internally, for example, ORI permits the filing of a “Small Organization Statement,” by which the institution agrees to report all allegations of misconduct to ORI, which will work with the institution to come up with an appropriate investigative process.⁸⁸ ORI’s regulations also make clear that the agency has the discretionary authority to “respond directly to any allegation of research misconduct at any time before, during, or after an institution’s response to the matter.”⁸⁹

⁸³ General Responsibilities for Compliance, 42 C.F.R. § 93.300 (2014).

⁸⁴ Institutional Policies and Procedures, 42 C.F.R. § 93.304 (2014).

⁸⁵ For example, the substance of an institution’s confidentiality policy is largely dictated by the instructions in 42 C.F.R. § 93.108, whereas it is essentially up to each institution to determine what constitutes a “thorough, competent, objective, and fair response to allegations of research misconduct.” 42 C.F.R. § 93.304(b) (2014). Although some consistency across policies is afforded by fact that all policies are subject to ORI’s approval and must comply with due process requirements, this is another area where in practice uniformity is subjugated to institutional decision-making. 42 C.F.R. § 93.304(c).

⁸⁶ Completing the Research Misconduct Process, 42 C.F.R. § 93.316(a) (2014).

⁸⁷ Federal Policy on Research Misconduct, 65 Fed. Reg. at 76,263.

⁸⁸ Assurances for Small Institutions, 42 C.F.R. § 93.303 (2014).

⁸⁹ General Statement of ORI Authority, 42 C.F.R. § 93.400 (2014).

The Allegation. An allegation of research misconduct can be made either in speech or in writing to an official of the research institution, the funding agency, or directly to ORI.⁹⁰ There is no reliable data on how many initial allegations of misconduct are filed with research institutions or who files them,⁹¹ but ORI data shows that a majority of the allegations that lead to reported investigations are, contrary to conventional wisdom, made by faculty rather than graduate students, laboratory technicians, or post-doctoral fellows.⁹² According to one study of ORI research misconduct investigations from 1994-2003 using data from ORI's own administrative case tracking system, 57 percent of whistleblowers had an academic rank of dean, professor, associate professor, or assistant professor, while only 19 percent were postdoctoral fellows, research associates/assistants, students, or technicians.⁹³ These numbers are consistent with an earlier 1995 study of whistleblowers from ORI's case files that found that found that 61.8 percent of respondents had the academic rank of professor, associate professor, or assistant professor, while only 8.8 percent were listed as graduate students or post-doctoral fellows, and 27.9 percent had no listed academic rank.⁹⁴

It is unsurprising that faculty members are more likely to report observed misconduct than lower ranked individuals in the lab hierarchy, given the reasonable notion that those with authority are more likely to speak out when they see something.⁹⁵

⁹⁰ See Allegation, 42 C.F.R. § 93.201 (2014) (establishing forms in which an allegation may be made).

⁹¹ Institutions are obligated to file an annual report listing the number of allegations they receive, but this count includes only allegations that make it past an initial assessment and reflects only those allegations the institution concludes fall within ORI's jurisdiction.

⁹² LAWRENCE J. RHOADES, ORI CLOSED INVESTIGATIONS INTO MISCONDUCT ALLEGATIONS INVOLVING RESEARCH SUPPORTED BY THE PUBLIC HEALTH SERVICE: 1994-2003, at 29-30 (2004) [hereinafter ORI CLOSED INVESTIGATIONS]. The proportion of non-faculty might actually be somewhat higher, because this group is likely well represented among the 25 percent of whistleblowers whose academic rank was anonymous, confidential, or otherwise unavailable.

⁹³ *Id.* at 17-18.

⁹⁴ RESEARCH TRIANGLE INST., CONSEQUENCES OF WHISTLEBLOWING FOR THE WHISTLEBLOWER IN MISCONDUCT IN SCIENCE CASES 12-13 (1995) [hereinafter CONSEQUENCES OF WHISTLEBLOWING].

⁹⁵ This is essentially the point raised by Malcolm Gladwell in *Outliers* when he noted that more airline accidents occur when the pilot is behind the controls than when the first mate is: pilots are much more willing to criticize or point out the errors of first mates than vice versa. MALCOLM GLADWELL, *OUTLIERS: THE STORY OF SUCCESS* 197 (2008).

Nonetheless, two points about the available data on whistleblowers cast some doubt on the accuracy of the numbers indicating a professorial reporting majority.⁹⁶ For one thing, the ORI data reflects only those whistleblowers whose allegations led to opening a case at ORI.⁹⁷ Assuming that individuals with less experience and less authority may be disadvantaged in putting together sufficiently specific allegations, it could be the case that a greater portion of the allegations made by students, fellows, and technicians never make it to the investigative stage.⁹⁸ Second—and paradoxically, if we accept that allegations made by those in authority have some advantage—the data suggest that allegations made by individuals lower on the institutional totem pole are actually more likely to result in a finding of misconduct than allegations made by faculty members.⁹⁹ While the sample sizes are unfortunately small, it is nonetheless noteworthy that research associates/assistants and students were most likely to have their allegations substantiated, at 64 percent and 58 percent respectively, and anonymous, unknown, or confidential complainants (a category likely to contain more of these more junior members of the community) had a substantiation rate of 55 percent, tied for third with full professors.¹⁰⁰ Lab technicians were the least likely to have their claims substantiated.¹⁰¹

These figures are in tension with the idea that higher ranking members of research institutions are the most likely or best situated whistleblowers, although more data, particularly relating to which types of whistleblowers are bringing allegations against which types of respondents, and with what level of success, are still sorely lacking.¹⁰² What we do know is that according to the 1995 whistleblower study, complainants who were the accused's superior or supervisor were less likely to suffer negative consequences from whistleblowing (76%) than those who were collaborators, colleagues, students or subordinates (83.3%).¹⁰³ The least likely to suffer any negative

⁹⁶ See ORI CLOSED INVESTIGATIONS, *supra* note 92, at 28–29 (describing the limitations of the data collected, and possibilities for future research).

⁹⁷ *Id.* at 3.

⁹⁸ See *id.* at 37–38 (noting that professors and associate professors most frequently make allegations of research misconduct).

⁹⁹ *Id.* at 37–38.

¹⁰⁰ *Id.* at 31–32.

¹⁰¹ *Id.* at 31–32.

¹⁰² See *id.* at 30–32.

¹⁰³ CONSEQUENCES OF WHISTLEBLOWING, *supra* note 94, at 27.

consequences were outside researchers or reviewers (47.1%).¹⁰⁴

When an allegation is made directly to ORI, that agency may either conduct its own initial assessment of the allegation or refer the matter to the relevant research institution for an assessment, inquiry, or other appropriate follow-up.¹⁰⁵ If ORI conducts an assessment, it initially determines whether each of three conditions is met: first, whether the allegation appears to fall within the definition of research misconduct; second, whether it appears to involve supported research; and third, whether it is “sufficiently specific so that potential evidence may be identified and sufficiently substantive to warrant an inquiry.”¹⁰⁶ If on the basis of this assessment ORI determines that an inquiry is warranted, it forwards the case to the “appropriate institution” for that purpose.¹⁰⁷ If it determines that an inquiry is not warranted, it will administratively close the matter at ORI and forward the allegation to the appropriate federal, state, or institutional entity for further appropriate action.¹⁰⁸ ORI administratively closes an allegation when it finds that the allegation falls outside ORI jurisdiction and cannot be referred to another agency, or has been resolved through further review and information.¹⁰⁹

A substantial number of allegations lack sufficiently specific information to permit a determination regarding appropriate disposition, and for these allegations ORI will take no action.¹¹⁰ These “no action” decisions are classified according to their origin and the action taken.¹¹¹ For example, if follow up is unnecessary, it will be coded “no action”, whereas a complaint that lacks sufficient specificity at the moment but about which additional information is expected, will be coded “no action possible now.”¹¹²

Approximately one-third of the allegations that are sufficiently specific and are within ORI’s jurisdiction ultimately result in a case being opened.¹¹³ ORI refers these cases to the institution

¹⁰⁴ *Id.* at 27.

¹⁰⁵ ORI Allegation Assessments, 42 C.F.R. § 93.402(a) (2014).

¹⁰⁶ *Id.* § 93.402(b).

¹⁰⁷ *Id.* § 93.402(c).

¹⁰⁸ *Id.* § 93.402(d)–(e).

¹⁰⁹ U.S. DEP’T OF HEALTH & HUMAN SERVS., OFFICE OF RESEARCH INTEGRITY ANNUAL REPORT 2011, at 11 (2011) [hereinafter 2011 ORI ANNUAL REPORT].

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *Id.*

where the questioned research took place to conduct an inquiry.¹¹⁴ The Federal Policy foresees referral to the institution as the default rule, though it makes clear that “at any time, the Federal agency may proceed with its own inquiry or investigation.”¹¹⁵ In some cases, an agency may elect not to refer an allegation to the research institution at all, including when:

the agency determines the institution is not prepared to handle the allegation in a manner consistent with this policy; agency involvement is needed to protect the public interest, including public health and safety; the allegation involves an entity of sufficiently small size (or an individual) that it cannot reasonably conduct the investigation itself.¹¹⁶

When an allegation is made directly to a research institution rather than to ORI, the institution has no duty to inform ORI at the assessment phase, and it has only a limited duty to notify ORI at the inquiry stage.¹¹⁷ Ordinarily, research institutions must notify the funding agency only if: “(1) the allegation involves Federally funded research (or an application for Federal funding) and meets the Federal definition of research misconduct given above, and (2) if the institution’s inquiry into the allegation determines there is sufficient evidence to proceed to an investigation.”¹¹⁸

Because the assessment of allegations occurs before a formal inquiry begins and need not typically be reported to ORI, it is a point in the process at which an institution can generally dispose of cases quietly, though there are special circumstances in which an institution is obliged to notify ORI about an allegation assessment.¹¹⁹ In a section entitled “Notifying ORI of Special Circumstances,” the ORI regulations make clear that at any time in a research misconduct proceeding, an institution must immediately notify ORI if it has reason to believe that:

- (a) Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
- (b) HHS resources or interests are threatened.
- (c) Research activities should be suspended.
- (d) There is reasonable indication of possible violations of civil or

¹¹⁴ *Id.* at 12; ORI Allegation Assessments, 42 C.F.R. § 93.402(c) (2014).

¹¹⁵ Federal Policy on Research Misconduct, 65 Fed. Reg. 76,260, 76,263 (Dec. 6, 2000).

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *Id.*

criminal law.

(e) Federal action is required to protect the interests of those involved in the research misconduct proceeding.

(f) The research institution believes the research misconduct proceeding may be made public prematurely so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved.

(g) The research community or public should be informed.¹²⁰

Inquiry. Once ORI or the institution determines in an assessment that an allegation satisfies the necessary prerequisites, an inquiry is opened.¹²¹ The purpose of the inquiry is “to conduct an initial review of the evidence to determine whether to conduct an investigation.”¹²² An inquiry “is solely intended to determine whether sufficient evidence exists to support conducting an investigation; it is not intended to answer the question of whether research misconduct actually occurred.”¹²³ While this limited purpose means that a full review of all the evidence related to the allegation isn’t necessary during an inquiry,¹²⁴ institutions are bound to both make a good faith effort to notify the respondent in writing and take “all reasonable and practical steps” to obtain, inventory, and sequester relevant research records and evidence “[a]t the time of or before beginning an inquiry.”¹²⁵ Under ORI regulations, institutions generally must complete an inquiry within 60 calendar days of its initiation.¹²⁶ Upon completion of the inquiry, the institution must prepare a written “inquiry report” only if it concludes that an investigation is warranted.¹²⁷ An investigation is warranted under ORI regulations if there is:

(1) A reasonable basis for concluding that the allegation falls

¹²⁰ Notifying ORI of Special Circumstances, 42 C.F.R. § 93.318 (2014).

¹²¹ Institutional Inquiry, 42 C.F.R. § 93.307(a) (2014) (“An inquiry is warranted if the allegation—(1) Falls within the definition of research misconduct under this part; (2) Is within § 93.102; and (3) Is sufficiently credible and specific so that potential evidence of research misconduct may be identified.”).

¹²² *Id.* § 93.307(c).

¹²³ Markey, *supra* note 34, at 76.

¹²⁴ 42 C.F.R. § 93.307(c).

¹²⁵ *Id.* § 93.307(b).

¹²⁶ *Id.* § 93.307(g).

¹²⁷ Reporting to ORI on the Decision to Initiate an Investigation, 42 C.F.R. § 93.309 (2014). Institutions are also required to submit inquiry reports to the agency regardless of the inquiry’s outcome if the inquiry was referred to the institution based on an allegation received directly by ORI. 2011 ORI ANNUAL REPORT, *supra* note 109, at 14.

within the definition of research misconduct under this part and involves PHS supported biomedical or behavioral research, research training or activities related to that research or research training, as provided in § 93.102; and

(2) Preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance.¹²⁸

The completed inquiry report must be made available to the respondent for review and comment,¹²⁹ and these comments, as well as any made by the complainant, must be attached to the report when it is submitted to ORI.¹³⁰ The report must also include, in addition to the basic elements of the complaint, the institution's basis for recommending that the alleged actions warrant an investigation.¹³¹ Beyond the required inquiry report, institutions must be able to provide ORI with the policies and procedures under which the inquiry was conducted and the records and evidence reviewed, and are required to keep detailed documentation of inquiries in which the institution decides not to investigate, sufficient to allow "a later assessment by ORI of the reasons why the institution decided not to conduct an investigation."¹³²

Neither the Federal Policy nor ORI's regulations specify who at a research institution is responsible for conducting inquiries.¹³³ Typically, the inquiry is conducted by either a single designated institutional official—frequently the institution's Research Integrity Officer ("RIO")—or an ad hoc or standing committee.¹³⁴ Many institutional policies designate a senior institutional official who then takes responsibility for appointing the person or persons who will actually conduct the inquiry.¹³⁵ A survey of institutional policies in the year 2000 showed that about 13 percent of institutions made a single official responsible for inquiries, while 68 percent used either an ad hoc or standing

¹²⁸ Institutional Inquiry, 42 C.F.R. § 93.307(d).

¹²⁹ 42 C.F.R. § 93.307(f).

¹³⁰ 42 C.F.R. § 93.309(a)(5).

¹³¹ *Id.* § 93.309(a)(4).

¹³² *Id.* § 93.309(c).

¹³³ *See id.* *See generally* 42 C.F.R. § 93.307 (governing procedures regarding inquiry reports).

¹³⁴ CHPS CONSULTING, ANALYSIS OF INSTITUTIONAL POLICIES FOR RESPONDING TO ALLEGATIONS OF SCIENTIFIC MISCONDUCT 6-2-6-3 (2000), available at http://ori.dhhs.gov/documents/institutional_policies.pdf [hereinafter ANALYSIS OF INSTITUTIONAL POLICIES].

¹³⁵ *Id.* at 6-3.

committee, and that at 12 percent of institutions a single official was most often involved in conducting the inquiry, while at 37 percent of institutions inquiries were most often conducted by a panel of three.¹³⁶

Other data suggests that institutions using a single official represent a significant share of the inquiries actually conducted: in the ten year period from 1994-2003, 22 percent of inquiries were conducted by single individuals, and nearly three-quarters of inquiries were conducted by panels of three or fewer.¹³⁷ The scope of an inquiry and the authority given to those who conduct it varies across institutions and is not dictated by federal regulations beyond 42 C.F.R. § 93.300's general admonition that institutions respond to allegations "in a thorough, competent, objective and fair manner."¹³⁸ The 2000 survey of institutional policies found that the most common authority given to those conducting inquiries was fact finding (77% of polices), while a smaller number of institutions authorized these officials to interview witnesses (38%), make the decision whether an investigation is warranted (42%) or make a recommendation about whether an investigation is warranted (29%).¹³⁹

Although the expectation under the ORI regulations is that most inquiries and investigations will be conducted by the relevant research institution, ORI also has the option of recommending that HHS conduct its own inquiry or investigation.¹⁴⁰ ORI believes that "[t]here will rarely be a need for HHS, rather than an institution, to conduct an inquiry or investigation, but if it is necessary, the OIG would carry out that responsibility."¹⁴¹ The number of inquiries and investigations carried out by HHS itself has indeed historically been low.¹⁴²

Investigation. Once an institution determines that an

¹³⁶ *Id.* at 6-4.

¹³⁷ ORI CLOSED INVESTIGATIONS, *supra* note 92, at 42.

¹³⁸ 42 C.F.R. § 93.300(b) (2014).

¹³⁹ ANALYSIS OF INSTITUTIONAL POLICIES, *supra* note 134, at 6-8.

¹⁴⁰ 42 C.F.R. § 93.400(a)(4) (2014). ORI cannot itself conduct such inquiries or investigations because, in light of ORI's authority to make findings of research misconduct, doing so would violate the separation of functions between investigation and adjudication required by 5 U.S.C. § 554(d) (2012). *See* Public Health Service Policies on Research Misconduct, 70 Fed. Reg. 28,370, 28,374-75 (May 17, 2005) (omitting statutory reference).

¹⁴¹ U.S. DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF RESEARCH INTEGRITY, QUESTIONS AND ANSWERS: 42 CFR PART 93 (2005), *available at* <http://ori.dhhs.gov/documents/QandA.reg.6-06.pdf>.

¹⁴² *See* ORI CLOSED INVESTIGATIONS, *supra* note 92, at 4-5.

investigation is warranted, it has 30 days to begin that investigation.¹⁴³ In addition to providing ORI with an inquiry report, the institution must also notify the respondent in writing before the investigation begins, and—if it failed to do so at the allegation and inquiry stages—take all “reasonable and practical steps” to secure the relevant research records and evidence.¹⁴⁴ The form of the investigation is largely left to the discretion of the research institution, although ORI does set certain minimum procedural standards.¹⁴⁵ For example, the agency requires institutions to make “diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision”¹⁴⁶

Likewise, institutions must “[t]ake reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practicable, including participation of persons with appropriate scientific expertise,” interview “each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation,” and diligently pursue “all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of research misconduct.”¹⁴⁷ Investigations must in principle be completed within 120 days, although extensions are available with ORI’s permission,¹⁴⁸ and in the ten-year period from 1994-2003 only 34 percent of investigations were completed in 120 days or less, while 19 percent took more than 300 days.¹⁴⁹ Beyond these basic requirements, the only other concrete instruction ORI provides institutions regarding conducting investigations is in relation to the mandatory “investigation report.”¹⁵⁰ The investigation report must lay out the allegations and basis for ORI jurisdiction, the investigation policies and procedures used,

¹⁴³ Institutional Investigation, 42 C.F.R. § 93.310(a) (2014).

¹⁴⁴ *Id.* § 93.310(b)–(d).

¹⁴⁵ *See generally id.* (setting forth some clear procedural requirements while providing the institution discretion in determining, for example, what “reasonable steps” to take).

¹⁴⁶ *Id.* § 93.310(e).

¹⁴⁷ *Id.* § 93.310(f)–(h).

¹⁴⁸ Investigation Time Limits, 42 C.F.R. § 93.311(b) (2014).

¹⁴⁹ ORI CLOSED INVESTIGATIONS, *supra* note 92, at 45.

¹⁵⁰ *See* Institutional Investigation Report, 42 C.F.R. § 93.313 (2014) (promulgating content requirements for final institutional investigation reports).

a summary of the research records and evidence reviewed, and a statement of findings.¹⁵¹ The regulations say nothing about who within an institution should conduct the investigation, other than the aforementioned requirement that they include “persons with appropriate scientific expertise.”¹⁵² Nor do they set forth any preferred or required procedures.¹⁵³

In practice, the overwhelming bulk (for 1994-2003, 80 percent) of investigations are conducted by ad hoc committees,¹⁵⁴ which in general are larger than inquiry panels (one-third of the policies in this period specified that the committee would have at least five members).¹⁵⁵ Though many institutions have similar policies developed along the lines of ORI’s Sample Policy and Procedures,¹⁵⁶ that document is non-binding and in substantial part simply reflects the general guidance laid out in the regulations.¹⁵⁷

When an institutional investigation is complete, the institution must provide the respondent with copy of the draft report and either a copy of, or supervised access to, the evidence on which it is based.¹⁵⁸ The respondent must, and the complainant may, be given the opportunity to file comments on that draft.¹⁵⁹ Once the institution’s deciding official¹⁶⁰ reviews the report, comments, and reaches a finding, the institution must forward certain information to the agency:

- (a) Investigation Report. Include a copy of the report, all attachments, and any appeals.
- (b) Final institutional action. State whether the institution found

¹⁵¹ Opportunity to Comment on the Investigation Report, 42 C.F.R. § 93.312 (2014).

¹⁵² 42 C.F.R. § 93.310(f).

¹⁵³ Public Health Service Policies on Research Misconduct, 70 Fed. Reg. 28,370, 28,373 (May 17, 2005).

¹⁵⁴ ANALYSIS OF INSTITUTIONAL POLICIES, *supra* note 134, at 6-4.

¹⁵⁵ *Id.* at 6-6.

¹⁵⁶ *See generally* DEP’T OF HEALTH & HUMAN SERVS., OFFICE OF RESEARCH INTEGRITY, SAMPLE POLICY AND PROCEDURES FOR RESPONDING TO ALLEGATIONS OF RESEARCH MISCONDUCT [hereinafter SAMPLE POLICY & PROCEDURES], available at <http://ori.hhs.gov/sites/default/files/SamplePolicyandProcedures-5-07.pdf>.

¹⁵⁷ *Id.* at 1.

¹⁵⁸ 42 C.F.R. § 93.312 (2014).

¹⁵⁹ *Id.*

¹⁶⁰ The deciding official is the institutional official who makes final determinations on allegations of research misconduct and any institutional administrative actions. The deciding official could theoretically be a committee or an individual, but “should have no prior involvement in the institution’s inquiry, investigation, or allegation assessment.” SAMPLE POLICY & PROCEDURES, *supra* note 156, at 2–3.

research misconduct, and if so, who committed the misconduct.

(c) Findings. State whether the institution accepts the investigation's findings.

(d) Institutional administrative actions. Describe any pending or completed administrative actions against the respondent.¹⁶¹

Adjudication & ORI Review. Adjudication has two parallel components, one at the institution and another at ORI.¹⁶² At the conclusion of an institutional research misconduct investigation, the committee that conducted the investigation compiles an investigation report, including the respondent's (and possibly the complainant's) comments, and makes a recommendation to the institution's deciding official for either dismissal of the claim or a finding of research misconduct.¹⁶³ The deciding official makes a finding, justifies it, and decides on appropriate institutional administrative actions, which may include withdrawal or correction of pending or published papers relying on or utilizing the tainted research, removal of the responsible person from the a project, imposition of conditions on that person's future work, restitution of funds, or initiation of steps leading to termination of employment.¹⁶⁴

Regardless of the institutional outcome, the records of inquiries and investigations (along with other elements detailed above) must be forwarded to ORI, which conducts its own review.¹⁶⁵ Thus, even in cases where an inquiry or investigation is terminated by an institution due to an admission of guilt or a settlement with the respondent (for example, where the respondent agrees to resign), ORI must be informed so it can conduct its own review.¹⁶⁶ In conducting its review, ORI may undertake additional investigative and oversight steps as necessary, including requesting additional information from the institution.¹⁶⁷ When it has completed its review, ORI either closes

¹⁶¹ Notice to ORI of Institutional Findings and Actions, 42 C.F.R. § 93.315 (2014). *See also* Federal Policy on Research Misconduct, 65 Fed. Reg. 76,260, 76,263 (Dec. 6, 2000) (stating that an institution must turn over "the evidentiary record, the investigative report, recommendations made to the institution's adjudicating official, and the subject's written response to the recommendations . . .").

¹⁶² SAMPLE POLICY & PROCEDURES, *supra* note 156, at 19–20.

¹⁶³ *Id.* at 16–19.

¹⁶⁴ *Id.* at 18–20.

¹⁶⁵ 42 C.F.R. §§ 93.315, 93.403 (2014); Federal Policy on Research Misconduct, 65 Fed. Reg. at 76,263.

¹⁶⁶ Markey, *supra* note 34, at 78.

¹⁶⁷ 42 C.F.R. § 93.403(d) (2014).

the case without a finding of research misconduct, finds that research misconduct occurred and seeks HHS approval of administrative actions, or recommends that HHS settle the case.¹⁶⁸ In practice, 80–90 percent of cases in which misconduct is found by the institution result in settlements with the government, an outcome that avoids the lengthy and costly process of litigating a misconduct finding through the agency appeals process and ultimately the courts.¹⁶⁹ HHS may settle with a respondent at any time, if it concludes that doing so would be in the best interests of the federal government and the public health or welfare.¹⁷⁰ If ORI does make a finding of research misconduct and propose HHS administrative actions,¹⁷¹ the agency will notify the respondent of the outcome by a “charge letter,” detailing the ORI findings, their basis, and any HHS administrative actions, and informing the respondent of the opportunity to contest the findings and administrative actions.¹⁷² Unless the respondent contests this charge letter within 30 days, ORI’s finding issues and the HHS administrative actions become final.¹⁷³

In deciding what administrative action to propose, ORI considers “the seriousness of the misconduct, and the need to protect the health and safety of the public, promote the integrity of the PHS supported research and research process, and conserve public funds.”¹⁷⁴ Among the aggravating and mitigating factors that go into this analysis are the degree to which the conduct was knowing, intentional, or reckless; whether it was “an isolated event or part of a continuing or prior pattern”; and its impact on the “research record, research subjects, other researchers, institutions, or the public health or welfare[.]”¹⁷⁵ In addition to administrative actions, the Federal Policy makes clear that agencies are supposed to “promptly refer” all criminal or civil fraud violations that they believe may have occurred to

¹⁶⁸ 42 C.F.R. § 93.404 (2014).

¹⁶⁹ ATL. INFO. SERVS., REPORT ON RESEARCH COMPLIANCE, TRUTH TELLING: ORI OFFICIALS OFFER DETAILS ON CASE SETTLEMENTS, OVERSIGHT REVIEWS 1 (2012).

¹⁷⁰ 42 C.F.R. § 93.409(a) (2014).

¹⁷¹ See 42 C.F.R. § 93.407 (2014) (providing a non-exclusive list of available HHS administrative actions).

¹⁷² 42 C.F.R. § 93.405 (2014).

¹⁷³ 42 C.F.R. § 93.406 (2014).

¹⁷⁴ 42 C.F.R. § 93.408 (2014).

¹⁷⁵ *Id.*; see also Federal Policy on Research Misconduct, 65 Fed. Reg. 76,260, 76,264 (Dec. 6, 2000).

the Department of Justice or an appropriate investigative body within the agency.¹⁷⁶

When an ORI finding of research misconduct becomes final or results in a settlement, ORI may provide final notification of its findings and the administrative actions being taken to the respondent, the institution, the complainant, and HHS officials.¹⁷⁷ If one of the administrative actions is suspension or debarment, the debarring official may provide separate notice of final agency action on that remedy.¹⁷⁸ ORI *may* also (1) identify publications requiring correction or retraction and prepare and send a notice to them; (2) publish notice of the research misconduct findings; (3) notify the respondent's current employer; and (4) take other actions authorized by law.¹⁷⁹ By contrast, when final HHS action does not result in either a settlement or a finding of research misconduct, the regulations say that ORI may provide written notice of this fact to the parties (respondent, institution, complainant, HHS officials), and take other actions authorized by law.¹⁸⁰

Two other regulations bear on what information may be disclosed when no finding of misconduct is reached.¹⁸¹ First, under the confidentiality provisions of ORI's regulations, disclosure of the identity of the respondent must be "limited, to the extent possible, to those who need to know," and all identifying records and evidence must likewise be "limited to those who have a need to know to carry out a research misconduct proceeding."¹⁸² Second, research institutions are required to take "[a]ll reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made."¹⁸³

¹⁷⁶ Federal Policy on Research Misconduct, 65 Fed. Reg. at 76,264.

¹⁷⁷ 42 C.F.R. § 93.411 (2014).

¹⁷⁸ *Id.*

¹⁷⁹ *Id.*

¹⁸⁰ 42 C.F.R. § 93.410 (2014). Respondents have a right of appeal to contest both ORI's determination and the consequences of that determination. 42 C.F.R. §§ 93.500, 93.501 (2014); *see also* Markey, *supra* note 34, at 81–82.

¹⁸¹ 42 C.F.R. §§ 93.108, 93.304 (2014).

¹⁸² 42 C.F.R. § 93.108.

¹⁸³ 42 C.F.R. § 93.304.

*B. The Role of the Food
& Drug Administration*

As the ultimate gatekeeper to the large and heavily regulated life-sciences marketplace, FDA has both a tremendous responsibility and tremendous authority.¹⁸⁴

While this article is not primarily about FDA, it is important to understand how this agency engages with research misconduct, both as a contrast to the Federal Policy and to understand that there is some redundancy built into the broader system (which may or may not suggest less need for rigorous enforcement in the first instance).¹⁸⁵ FDA's statutory mandate is to "protect the public health by ensuring that . . . human and veterinary drugs are safe and effective . . . [and] there is reasonable assurance of the safety and effectiveness of devices intended for human use."¹⁸⁶ The tools FDA uses to address research misconduct reflect its public-health oriented mission, and it is important to consider this difference relative to the two purposes served by the Federal Policy—*viz.*, protecting federal funds and preventing the corruption of the research record.¹⁸⁷

As a general matter, FDA assesses data submitted in support of regulatory applications¹⁸⁸ for its sufficiency for that purpose.¹⁸⁹ Thus the agency's basic response to "bad" data (whatever its particular causes) is simply to reject the application this data is submitted to support, or at least request additional information.¹⁹⁰ For example, consider the agency's regulations laying out the conditions for refusal to approve a New Drug Application:

¹⁸⁴ U.S. DEP'T OF HEALTH & HUMAN SERVS., *About FDA*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/default.htm> (last visited Jan. 31, 2015).

¹⁸⁵ *See generally* Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities; Final Policy, 56 Fed. Reg. 46,191 (Sept. 10, 1991) (issued as Compliance Policy Guide (CPG) 7150.09) [hereinafter AIP CPG] (outlining the FDA's general approach for its review and approval process).

¹⁸⁶ Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 393(b) (2012) [hereinafter FDCA].

¹⁸⁷ *Id.*; Federal Policy on Research Misconduct, 65 Fed. Reg. 76,260, 76,263 (Dec. 6, 2000).

¹⁸⁸ The FDA defines an "application" as "any application, petition, amendment, supplement, or other submission made by an applicant to an agency review process in support of the approval or marketing of a regulated product." *See* Markey, *supra* note 34, at 83.

¹⁸⁹ *Id.*

¹⁹⁰ Refusal to Approve an Application, 21 C.F.R. § 314.125(3)(b) (2014).

FDA may refuse to approve an application for any of the following reasons: . . .

(4) There is insufficient information about the drug to determine whether the product is safe for use . . .

(5) There is a lack of substantial evidence consisting of adequate and well-controlled investigations . . . that the drug product will have the effect it purports . . .

(7) The application contains an untrue statement of a material fact. . . .

(12) The applicant does not permit a properly authorized officer or employee of the [FDA] an adequate opportunity to inspect the facilities, controls, and any records relevant to the application. . . .

(14) The application does not contain an explanation of the omission of a report of any investigation of the drug product sponsored by the applicant, or an explanation of the omission of other information about the drug pertinent to an evaluation of the application that is received or otherwise obtained by the applicant from any source.

(15) A nonclinical laboratory study that is described in the application and that is essential to show that the drug is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling was not conducted in compliance with the good laboratory practice regulations in part 58 of this chapter and no reason for the noncompliance is provided or, if it is, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study.

(16) Any clinical investigation involving human subjects described in the application, subject to the institutional review board regulations in part 56 of this chapter or informed consent regulations in part 50 of this chapter, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected.¹⁹¹

Most forms of unreliable data could fall under one of these provisions, particularly given their incorporation of the agency's Good Laboratory Practice for Nonclinical Studies¹⁹² and Protection of Human Subjects regulations.¹⁹³ FDA also directly polices the conduct of clinical research, which generally must be conducted under an FDA-approved investigatory new drug

¹⁹¹ *Id.*

¹⁹² See Good Laboratory Practice for Nonclinical Laboratory Studies, 21 C.F.R. § 58 (2014).

¹⁹³ See Protection of Human Subjects, 21 C.F.R. § 50 (2014).

application (“IND”).¹⁹⁴ The regulations governing INDs cover research misconduct largely through prohibitions on: (1) deviating from the protocols approved by FDA and (2) making untrue statements of material fact or omitting material information in reports to the agency, both of which are sufficient grounds for either terminating the IND¹⁹⁵ or disqualifying the clinical investigator.¹⁹⁶

In addition to these routine ways that FDA regulates research misconduct, the agency also has a specific policy in place to deal with situations where there is “a pattern or practice of wrongful conduct that raises a significant question regarding the reliability of the data in an application.”¹⁹⁷ Because the Application Integrity Policy (“AIP”) was technically issued as a Compliance Policy Guide, which by definition is merely a staff directive to FDA employees, it does not legally bind either FDA or regulated parties.¹⁹⁸ Accordingly, the AIP might best be understood simply as an articulation of the agency’s approach to reviewing applications that might be affected by unreliable data, and investigating the wrongful acts that call that data into question.¹⁹⁹

The gist of the AIP is that when FDA has reason to believe that data submitted by an applicant²⁰⁰ is unreliable due to some “pattern or practice” of misconduct on the part of the applicant,²⁰¹ it may invoke the AIP, leading to (1) suspension of all substantive scientific review of the applicant’s pending applications potentially affected by these acts, and (2) the initiation of a “validity assessment” in which the agency undertakes “to identify all instances of wrongful acts and to determine the extent to which the wrongful acts may [have]

¹⁹⁴ See Requirement for an IND, 21 C.F.R. § 312.20 (2014).

¹⁹⁵ Termination, 21 C.F.R. § 312.44(b)(1) (2014).

¹⁹⁶ Disqualification of a Clinical Investigator, 21 C.F.R. § 312.70 (2014).

¹⁹⁷ AIP CPG, *supra* note 185.

¹⁹⁸ Paula R. Katz, *Protecting the Public’s Health Through the Application Integrity Policy*, 65 FOOD & DRUG L.J. 539–41 (2010).

¹⁹⁹ *Id.*

²⁰⁰ An “applicant” for purposes of the AIP means person “who submits to FDA data or other information to influence or support an agency decision regarding approval to market an FDA-regulated product. Actions by an applicant’s employees or agents are considered actions by the applicant.” AIP CPG, *supra* note 185.

²⁰¹ Examples of actions that “subvert the integrity of an FDA review process” include “submitting fraudulent applications, making untrue statements of material facts, or giving or promising bribes or illegal gratuities.” AIP CPG, *supra* note 185.

affected approved or pending applications.”²⁰²

The AIP Committee, an agency committee made up of representatives from each Center and the Office of Regulatory Affairs and responsible for promoting consistent implementation of the policy, has clarified that although invocation of the AIP may cover one, several, or all of the applications filed by an applicant (including applications involving more than one research facility), ordinarily when a wrongful act raises significant questions about reliability of data in only a single application, the AIP need not be invoked “unless the review process is inadequate to deal with the data integrity issues raised by the wrongful act.”²⁰³

In a marked contrast with presumption of innocence operative in research misconduct investigations under the Federal Policy on Research Misconduct, the suspension of scientific review (or, where merited, the withdrawal of prior approvals) under the AIP essentially puts the burden on the suspect applicant to allay FDA’s concerns.²⁰⁴ In this vein, the AIP describes several corrective applications that FDA expects applicants to take before it will revoke the AIP. Applicants are expected to:

1. Cooperate fully with FDA and other Federal investigations to determine the cause and scope of any wrongful acts and to assess the effects of the acts on the safety, effectiveness, or quality of products;
2. Identify all individuals who were or may have been associated with or involved in the wrongful acts and ensure that they are removed from any substantive authority on matters under the jurisdiction of FDA;
3. Conduct a credible internal review designed to identify all instances of wrongful acts associated with applications submitted to FDA The internal review is intended to supplement FDA’s ongoing, comprehensive investigation to identify all instances of wrongful acts. The internal review should involve an outside consultant or a team of consultants who are qualified by training and experience to conduct such a review. . . . ;
4. Commit, in writing, to developing and implementing a corrective action operating plan to assure the safety, effectiveness, and quality of their products. This commitment ordinarily will be in the

²⁰² AIP CPG, *supra* note 185; *see also* Katz, *supra* note 198 at 539, 541.

²⁰³ OFFICE OF REGULATORY AFFAIRS, APPLICATION INTEGRITY POLICY PROCEDURES 10 (1998), *available at* <http://www.fda.gov/downloads/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm072631.pdf>.

²⁰⁴ Katz, *supra* note 198, at 539.

form of a consent decree or agreement, signed by the president, chief executive officer, or other official most responsible for the applicant's operations, and submitted to FDA. The corrective action operating plan will, as appropriate, address procedures and controls to preclude future instances of wrongful acts and noncompliance with regulatory requirements for approved applications, as well as procedures and controls to preclude any recurrences of other violations which may have been found (e.g., a comprehensive ethics program).

FDA intends to reinspect the applicant to determine that the internal review has been satisfactorily completed and that the applicant's written corrective action operating plan has been satisfactorily implemented.²⁰⁵

In short, if an applicant hopes to have its application undergo the substantive review necessary to make it onto the market, it not only must conduct a full internal review using hired outside experts, but also must fully cooperate (even to the extent of incriminating its employees or contractors) with a comprehensive external review conducted by FDA, and must bind itself to a corrective action plan for which its executives will take personal responsibility.²⁰⁶ If upon completion of the applicant's internal audit and FDA reinspection, the agency concludes that data in an application actually are unreliable, it will ordinarily refuse to approve the application (or in the case of a prior approval, it will withdraw it), requiring the applicant to file a new application (rather than allowing it to correct the data using a far faster and less expensive amendment or supplement).²⁰⁷ The truth and accuracy of the data in such a new application "should be certified by the president, chief executive officer, or other official most responsible for the applicant's operations."²⁰⁸

A direct comparison of the Federal Policy with the AIP would undoubtedly be an unfair one: the two policies not only protect different interests, they also protect these interests under distinctly different circumstances.²⁰⁹ The AIP comes into play primarily at the market-approval stage in drug development, when undetected misconduct could directly endanger the public

²⁰⁵ AIP CPG, *supra* note 185, at 46,200.

²⁰⁶ Katz, *supra* note 198, at 541.

²⁰⁷ AIP CPG, *supra* note 185, at 46,200.

²⁰⁸ *Id.*

²⁰⁹ Compare AIP CPG, *supra* note 185, at 46,200, with Federal Policy on Research Misconduct, 65 Fed. Reg. 76,260, 76,263 (Dec. 6, 2000) (discussing different applicable situations).

health, whereas much of the research covered by the Federal Policy is basic research or research years away from introduction into consumer products.²¹⁰ Moreover, the two policies operate in tandem, so that the AIP protects the public against the most dangerous forms of misconduct under the Federal Policy.²¹¹ Nonetheless, some comparisons are useful, if only because they reflect the differences between two regulatory models that exist in the real world.²¹² Most significantly, whereas the Federal Policy's hallmarks are deference to research institutions and the presumption of innocence, the AIP simultaneously shifts the burden to defend their data onto applicants' shoulders and refuses to trust applicants to investigate and respond to misconduct in-house.²¹³

FDA polices research misconduct by withholding federal benefits pending proof of innocence, sending in federal inspectors, requiring third-party auditors, and requiring those at the top of applicants' corporate hierarchies to take personal responsibility for the conduct of their inferiors.²¹⁴ The Federal Policy allows research institutions to keep their federal grants until misconduct is definitely proven, and allows the institutions to conduct the investigation of allegations with their own staff, under their own policies, applying their own community standards.²¹⁵ Ultimately, a finding of misconduct under the Federal Policy punishes individual researchers, leaving their institutions largely immune from direct consequences.²¹⁶ Neither policy is necessarily superior—indeed they respond to substantially different problems—but the philosophic differences between the two regimes are striking.

²¹⁰ See Federal Policy on Research Misconduct, 65 Fed. Reg. at 76,261; see also AIP CPG, *supra* note 185, at 46,199–200.

²¹¹ See generally AIP CPG, *supra* note 185, at 46, 199–200 (examining the stages of the research process AIP is intended to protect); see also Federal Policy on Research Misconduct, 65 Fed. Reg. at 76,262.

²¹² See generally Markey, *supra* note 34, at 67–68 (describing various models and the stages of research they are intended to protect).

²¹³ See Federal Policy on Research Misconduct, 65 Fed. Reg. at 76,262–63; AIP CPG, *supra* note 185, at 46,200.

²¹⁴ See Markey, *supra* note 34, at 83–84.

²¹⁵ See Federal Policy on Research Misconduct, 65 Fed. Reg. at 76,262.

²¹⁶ *Id.* at 76,263.

*C. Non-Regulatory Approaches:
Juries and Journals*

In addition to the federal regulatory frameworks described above, there are several non-regulatory approaches to preventing, discovering, and punishing research misconduct.²¹⁷ First, there are several ways research misconduct can be addressed through the courts rather than administrative agencies.²¹⁸ Two important potential bases for litigation are the False Claims Act (“FCA”), and federal fraud and false statements laws.²¹⁹ Second, the peer-review system employed by scientific journals can potentially serve as an important mechanism for identifying and responding to some forms of scientific misconduct.²²⁰ While this article is intended primarily to address the shortcomings of and some potential adjustments to the regulatory responses, it is important to at least briefly discuss these non-regulatory responses and their limitations as substitutes for regulation.

A basic problem with resolving research misconduct allegations through the courts, whether through civil litigation or criminal prosecutions, is that determinations of misconduct in this area frequently require a sophisticated understanding of scientific methods and principles that courts and juries rarely possess and are often badly positioned to obtain, even with assistance from expert witnesses.²²¹ While this alone may not be enough of an impediment to rule out judicial remedies (certainly there are many highly technical domains where we nonetheless rely on judges and juries, and of course in some cases very little scientific knowledge will actually be needed), it is sufficient to raise serious doubts.²²² Moreover, there are other potential issues with attempting to use the existing false claims and false statements statutes to pursue research misconduct, including unresolved questions about how these laws might apply to individuals who, though guilty of misconduct, are not the principal investigators

²¹⁷ See generally Steinberg, *supra* note 56, at 64–68 (discussing different approaches to preventing research misconduct, such as increased self-regulation and peer-review).

²¹⁸ See Markey, *supra* note 34, at 84–85.

²¹⁹ See *id.* at 85.

²²⁰ See *id.* at 89–90.

²²¹ See *id.* at 84–87.

²²² See generally *id.* at 84–86 (outlining different issues that have arisen in relying on judicial remedies).

for a grant (and thus not the individuals who “certified” to compliance)²²³ and concerns driven by the fact that the FCA is fundamentally remedial and thus ill-suited as a tool for punishing misconduct where the actual harm—i.e., the size of the federal grant involved—may be small,²²⁴ even though the harm to society may be substantial and, indeed, incommensurate with the amount of money involved.²²⁵ Finally, the courts simply do not offer meaningful advantages over handling these matters via regulation.²²⁶ The costs of judicial enforcement are high, the process is slow, and the presumptively open nature of judicial proceedings arguably exacerbates rather than ameliorates concerns about respondent and whistleblower confidentiality.²²⁷ This is not to say there will not be some instances where the use of judicial remedies is warranted.²²⁸ For example, it may be appropriate in certain situations for FDA to refer a case for criminal prosecution when it discovers intentional fraud in the reporting of clinical studies of investigational new drugs.²²⁹

In line with the existing deferential attitude favoring scientific self-regulation of research, peer review by scientific journals is often offered as a complement to institutional self-policing in ferreting out and correcting scientific misconduct.²³⁰ Given the substantial importance attached to publication in academic circles and the high level of expertise of journal peer-reviewers, the argument is that journals are both uniquely situated to detect suspect research, to correct the scientific record, and—through a form of public shaming—deter future misconduct.²³¹ For several reasons, however, it is doubtful that journals could actually serve this role satisfactorily.²³²

²²³ See *id.* at 89.

²²⁴ See Goldberg, *supra* note 11, at 51–52 (noting that is unlikely for the government to ever prosecute health care fraud where the amount of money in controversy is de minimis).

²²⁵ See *id.* at 53–54.

²²⁶ See Jacqueline D. Wright Bonilla, *Illusory Protections For Those Accused of Scientific Research Misconduct: Need For Reform*, 16 J. TECH. L. & POL'Y, 107, 116–17 (2011).

²²⁷ *Id.*

²²⁸ See PETER BARTON HUTT ET AL., *FOOD AND DRUG LAW: CASES AND MATERIALS* 625 (Found. Press, 3d ed. 2007) (providing cases where judicial remedies were utilized).

²²⁹ See *id.* (noting occurrence of such referrals).

²³⁰ See Steinberg, *supra* note 56, at 64.

²³¹ See *id.* at 64, 66 (emphasizing the importance of interdisciplinary self-regulation).

²³² See *id.* at 67.

First, it is not clear that even after an article has been retracted or refuted, the scientific literature is meaningfully “purged” of the effects of the bad research.²³³ Indeed, Markey cites several studies indicating that retracted publications are frequently cited or relied upon by subsequent researchers, notwithstanding the publicly announced retractions.²³⁴ Second, evidence suggests that even absent “misconduct” in the sense this article is most concerned with, a substantial portion of published scientific data cannot be replicated.²³⁵ This raises questions regarding publications’ capacity to consistently identify “bad” research.²³⁶ Third, unlike regulators, scientific journals have neither the authority to compel institutions to investigate suspect research nor the resources to conduct such investigations themselves.²³⁷

III. FIVE PROBLEMS WITH THE CURRENT FEDERAL POLICY

When the HHS Commission on Research Integrity met in 1994 and 1995 to address the “apparent failure” of ORI and the still newly minted 1989 federal scientific misconduct regulations “to solve the important ethical, scientific, social, and legal problems posed by allegations against scientists of misconduct in research,”²³⁸ five “principal issues” emerged from the debate as needing to be addressed: (1) the definition of research misconduct, (2) the type and amount of process owed to accused scientists, (3) the appropriate degree of federal oversight of research institutions, (4) the protection of whistleblowers, and (5)

²³³ See Markey, *supra* note 34, at 92; Athina Tatsioni et al., *Persistence of Contradicted Claims in the Literature*, 298 J. AM. MED. ASS’N. 2517, 2517 (2007) (concluding that claims from highly cited observational studies persist and continue to be supported in the medical literature despite strong contradictory evidence from randomized trials).

²³⁴ Markey, *supra* note 34, at 92–93.

²³⁵ See Gautam Naik, *Scientists’ Elusive Goal: Reproducing Study Results*, WALL ST. J., Dec. 2, 2011, <http://www.wsj.com/articles/SB10001424052970203764804577059841672541590> (discussing the prevalence of medical research which cannot be replicated).

²³⁶ *Id.*

²³⁷ See Markey, *supra* note 34, at 93 (citing Harold C. Sox & Drummond Rennie, *Research Misconduct, Retraction, and Cleansing the Medical Literature: Lessons from the Poehlman Case*, 144 ANNALS INTERNAL MED. 609 (2006)).

²³⁸ COMM’N ON RESEARCH INTEGRITY, U.S. DEP’T OF HEALTH & HUMAN SERVS., INTEGRITY AND MISCONDUCT IN RESEARCH: REPORT OF THE COMMISSION ON RESEARCH INTEGRITY 1 (1995), available at http://ori.hhs.gov/images/ddblock/report_commission.pdf.

the role of the federal government in encouraging and supporting programs to prevent misconduct.²³⁹ As mentioned above, this article focuses primarily on the third of these, federal oversight, though it does not do so from a belief that the other issues are unimportant. Within the broad category of federal oversight, five deficiencies of the current regime are worth particularly considering.

A. *Assessing the Problem: The Problem With Inadequate Reporting Requirements.*

There is an problematic lack of empirical evidence about the true scope of misconduct in federally funded research.²⁴⁰ What we do know comes from a combination of surveys measuring researcher observations, the annual reports filed by federally funded research institutions each year,²⁴¹ and data published by ORI relating to those allegations directly received by ORI (rather than an institution) and relating to cases that trigger more detailed reporting requirements from institutions—generally those that proceed to the investigation stage.²⁴² What is missing in all these data sources is a reliable indicator of the true number of allegations of research misconduct received by institutions each year. Officially, institutions are obligated to include in their annual reports statistics on all “alleged research misconduct involving PHS-supported research, research training, or other research-related activities.”²⁴³ But based on discrepancies between expected and actual reporting numbers, some commentators have suggested that institutions are guilty of underreporting. It would not be altogether surprising if this were the case, given that research institutions have various incentives to downplay allegations of research misconduct: misconduct cases endanger both institutional reputation and the revenue generated by funded research, and investigating these cases is

²³⁹ *Id.* at 3.

²⁴⁰ C. Beth Sise, *Scientific Misconduct in Academia: A Survey and Analysis of Applicable Law*, 28 SAN DIEGO L. REV. 401, 405 (1991).

²⁴¹ See Institutional Compliance with Assurances, 21 C.F.R. § 93.302(b) (2014); DEP’T OF HEALTH & HUMAN SERVS., PUB. HEALTH SERV. FORM 6349, INSTITUTIONAL ASSURANCE AND ANNUAL REPORT ON POSSIBLE RESEARCH MISCONDUCT (Oct. 2014), available at <http://www.hhs.gov/forms/phs6349.pdf>.

²⁴² See, e.g., ORI CLOSED INVESTIGATIONS *supra* note 92, at 3 (discussing data collected only after it was reported by institutions).

²⁴³ U.S. DEP’T OF HEALTH & HUMAN SERVS., OFFICE OF RESEARCH INTEGRITY 2012 ANNUAL REPORT at 25 (2012) [hereinafter 2012 ORI ANNUAL REPORT].

time-consuming and expensive.²⁴⁴

One recent study found that 2,212 NIH-funded researchers observed 201 instances of likely misconduct over a three-year period between 2002 and 2005, or roughly three incidents per 100 researchers per year.²⁴⁵ Extrapolated to all NIH-funded researchers, this finding conservatively suggests that NIH-funded researchers as a group observed 2,325 instances of probable research misconduct per year.²⁴⁶ Even taking into account that a substantial share of observations go unreported to institutional officials (the study found that only 58 percent of observations were reported in the sample), the numbers still suggest that approximately 1,350 incidents of probable misconduct were reported each year to institutional officials.²⁴⁷ This figure is dramatically larger than the roughly 155 new allegations per year that institutions actually reported to ORI over the ten year period from 2002 to 2011.²⁴⁸

One possible explanation for the discrepancy would be that the “missing” allegations were not reportable to ORI because they did not relate to PHS-funded research activities. Although institutions are not obligated to disclose this information, one way to test this theory is to look at the more complete information available about allegations directly received by ORI. ORI tracks both the total number of allegations it receives and the share of those allegations that are actually within its jurisdiction, so we can use those numbers to calculate the share of allegations to institutions that we would expect to be reportable.

Table 1 shows the number of allegations directly received by ORI (or received by NIH and reported to ORI) over the six-year period from 2006-2011. As the table shows, of the 1,415 allegations received by ORI from 2006 to 2011, the agency coded only 441 (31.2%) as “pre-inquiry assessments” (“PIAs”), meaning that the agency assessed these allegations in detail.²⁴⁹ ORI determined that the rest of the allegations were either outside of ORI’s jurisdiction or lacked sufficient specific information to

²⁴⁴ See Sandra L. Titus et al., *Repairing Research Integrity*, 453 NATURE 980, 981 (2008) (discussing reasons institutions may not want to report misconduct).

²⁴⁵ *Id.* at 980.

²⁴⁶ *Id.*

²⁴⁷ *Id.* at 981.

²⁴⁸ See 2012 ORI ANNUAL REPORT, *supra* note 243, at 25.

²⁴⁹ See *id.* at 12 (defining “pre-inquiry assessment”).

permit a determination regarding disposition.²⁵⁰

	2006	2007	2008	2009	2010	2011	Total
Allegations Received	217	201	179	155	240	423	1,415
Pre-Inquiry Assessment Assigned	48	54	62	58	84	135	441 (31.2%)

Bearing in mind that it is possible that institutions might receive more misconduct allegations that fall outside of ORI's jurisdiction than ORI does, the 31.2% share of allegations that ORI determined merited further review is a useful benchmark. Applied to the 1,350 allegations that the data suggest institutions receive each year, we would expect around 421 of the allegations to be reportable to ORI. Even if institutions receive far more allegations that fall outside of ORI's jurisdiction than ORI does, there remains a major discrepancy between what we would expect institutions to report and what they are actually reporting.

Whatever other insights we can draw from the data, perhaps the most important point is simply that we lack reliable information about what is going on at institutions at the initial allegation-assessment stage. There is no clear justification for not requiring institutions to report *every* allegation they receive. Given that institutions presumably keep records of the allegations and inquiries they receive and oversee anyway, it would not require significant additional time, effort, or expense to send substantially all of this information along ORI. And while confidentiality concerns may arise about who gets to use this information and how, the mere collection of this data by the

²⁵⁰ See *id.* (describing situations in which ORI does not assign a PIA to an allegation).

²⁵¹ See 2012 ORI ANNUAL REPORT, *supra* note 243, at 13; 2011 ORI ANNUAL REPORT, *supra* note 109, at 13; U.S. DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF RESEARCH INTEGRITY, ANNUAL REPORT 13 (2010); U.S. DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF RESEARCH INTEGRITY, ANNUAL REPORT 8 (2009); U.S. DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF RESEARCH INTEGRITY, ANNUAL REPORT 6 (2008); U.S. DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF RESEARCH INTEGRITY, ANNUAL REPORT 4 (2007).

federal government should not be problematic: the record of agencies like FDA, the patent office, and myriad others suggests that with sufficient protections regarding disclosure, regulated scientists can trust in the government's ability to keep their information confidential.

*B. Who are the Detectives?
Inexperience & Conflicts of Interest*

Generally, the individuals who assess an allegation of misconduct or conduct a research misconduct inquiry or investigation are a respondent's peers or perhaps university administrators. Usually, these peers or administrators come from a "researcher's home institution," though in some special cases, like where the researcher "has switched institutions, it may be more appropriate for the institution where the alleged research misconduct occurred to respond," because it "may have better access to the evidence and witnesses."²⁵²

There are many good reasons to entrust the investigation of research misconduct to scientists rather than laymen, and there is something to be said for the familiarity a respondents' institutional peers may have with the organization, or with the idiosyncrasies of how research is conducted there, or with the specific research or personalities involved. Nonetheless, an allegation of research misconduct is a serious charge, both for the accused, whose career and reputation is at stake, and for the taxpayers, who frequently have millions of dollars on the line.

The delegation serious police work to peers and administrators raises red flags for at least two reasons. First, institutions and especially co-faculty frequently have a conflict of interests in investigating a member of their own community.²⁵³ Even assuming an impeccable commitment to conducting fair and unbiased investigations, it is worth reflecting on the fact that this system asks participants to take steps that could be career-ending for a person they know, have worked with, and is perhaps

²⁵² Federal Policy on Research Misconduct, 65 Fed. Reg. 76,260, 76,262 (Dec. 6, 2000).

²⁵³ The DOJ attorney who prosecuted Eric Poehlman noted that "[t]here are conflicting influences on a university where they are the co-grantor and responsible to other investigators. . . . For the system to work, the university has to be very ethical." Jeneen Interlandi, *An Unwelcome Discovery*, N.Y. TIMES, Oct. 22, 2006, http://www.nytimes.com/2006/10/22/magazine/22science_fraud.html?pagewanted=all.

even a friend.²⁵⁴ Even in our criminal justice system, where we cherish the right to a trial before a jury of our “peers,” jurors with a personal relationship to the defendant are regularly dismissed for cause.

Second, research misconduct investigations are rare—exceedingly so at small institutions with less expansive research programs.²⁵⁵ Given the complexity of the cases, their sensitivity, and the stakes involved for both the accused and, quite often, the whistleblower, it is at least worth considering whether such investigations might benefit from more experienced investigators. To once again draw on an analogy to our criminal justice system, no prosecutor starts their career trying homicides, and no police officer begins theirs by investigating them. The stakes are simply too high to entrust individuals with little or no relevant experience, even if they are bright, talented, and committed to doing a good job.

*C. Illusions of Uniformity:
Deference and Delegation*

The Federal Policy grants substantial discretion to recipients of federal research funds to set their own policies and procedures for investigating research fraud, and defers to the accepted practices of particular research communities in defining misconduct to begin with. While some degree of customization of policies and procedures allows a unified scheme to be adapted to the needs and available resources at research institutions large and small, the amount of variation permitted under the regulations renders the concept of a unified national policy a nullity.²⁵⁶ Though in practice many or most institutions may adopt similar procedures,²⁵⁷ the fact remains that identical

²⁵⁴ See *Research Misconduct*, GA. INST. OF TECH., <http://rcr.gatech.edu/research-misconduct> (last visited Jan. 31, 2015).

²⁵⁵ LOGICON/ROW SCIENCES, ORGANIZING AN INSTITUTIONAL INVESTIGATION ASSISTANCE PROGRAM: A FEASIBILITY STUDY FOR THE OFFICE OF RESEARCH INTEGRITY iii (2002), available at http://ori.hhs.gov/sites/default/files/organize_investigation_final.pdf.

²⁵⁶ See discussion *supra* Part II.A; see also Pascal, *supra* note 38, at 797–98.

²⁵⁷ Lind’s 2005 study did not assess the substantive similarity among policies, but her conclusions about the relative completeness of different institutions’ policies provide a valuable insight into the degree of variation across policies. She found that across the top twenty-five universities as ranked by NIH and NSF grant awards, nearly all provided complete information on elements including the content of inquiry and investigation reports and the rights of respondents. By contrast, there was tremendous variability in the

complaints filed at two universities could be handled under policies with differences material to the outcome of the case. Whether it is in the scope of protection granted to whistleblowers, the relative roles of administrators and academics, the powers granted to investigative bodies, or even the accused's right to be represented by an attorney, broad variation is accepted. This means that similarly situated researchers at different institutions can be subjected to materially different processes that afford them different protections.

As for defining research misconduct as a significant departure from accepted practices of the relevant research community, this presents both difficult line drawing problems and, again, the possibility of holding similarly situated individuals to disparate standards. For example, assume that there are two cross-disciplinary researchers and each dropped certain values from their reports after concluding that these values were statistical noise. Their respective institutions not only might reach different conclusions about *which* research community's accepted practices to judge by, but they might also disagree about *what* the accepted practices of a given research community may be.

The conduct of research today is national in scope: funding, whether public or private, is sought on a nationally competitive market; publication is in national journals; the academic job market is a national one; patents are federally granted and enforced; and the conditions for FDA approval of a new drug are the same regardless of where the molecule was discovered or the clinical tests conducted. In this world, it is anachronistic to think that researchers cannot be held to unified norms, nor research institutions expected to apply consistent policies to all recipients of federal research dollars, regardless of what state they are in.

*D. Access to Relevant Information:
Confidentiality & Information
Dissemination Structures*

Current rules prevent federal agencies and research institutions from making information about unsubstantiated past

completeness of information on other elements of the institutional policies, such as elements relating to ensuring fairness by maintaining confidentiality or requiring appropriate expertise from research integrity committee members. Lind, *supra* note 20, at 253–55.

allegations of research misconduct available.²⁵⁸ Out of a valid concern for the impact that such allegations can have on the reputations and careers of researchers, the Federal Policy not only limits the amount of information institutions must share with ORI, but it expressly limits the information either institutions or ORI can disseminate absent a finding of misconduct, and affirmatively commands institutions (the only actors that currently have access to full information about any given inquiry or allegation) to take steps to repair the reputations of victims of unsubstantiated allegations.²⁵⁹ At the same time, the ORI regulations make clear that the duties of institutions conducting research misconduct investigations include considering evidence of incidents of misconduct other than the one alleged: they must “[p]ursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion.”²⁶⁰

How exactly institutions are supposed to do this if such incidents occurred at other institutions is left to the imagination, because nowhere in the regulations are research institutions compelled to share information about such “additional instances” with one another.²⁶¹ To the contrary, safeguards for respondents’ confidentiality pose a serious obstacle to the sharing of valuable information about alleged violators.²⁶²

There is a valid interest in not prejudicing present decisions about findings of misconduct with past ones, particularly ones that led to dismissal. There is a valid interest in keeping information about prior unsubstantiated allegations out of the decision making process for awarding federal funding grants. But there is also a valid interest in allowing those investigating a given allegation to access records of past allegations.²⁶³ Research fraud is often complex and difficult-to-detect, and having a sense

²⁵⁸ See, e.g., Federal Policy on Research Misconduct, 65 Fed. Reg. 76,260, 76,262 (Dec. 6, 2000).

²⁵⁹ *Policies - Regulations*, OFFICE OF RESEARCH INTEGRITY, <http://ori.hhs.gov/policies-regulations-reg-6-05> (last updated May 7, 2013).

²⁶⁰ Institutional Investigation, 42 C.F.R. § 93.310(h) (2014).

²⁶¹ *Policies - Regulations*, *supra* note 259.

²⁶² See Confidentiality, 42 C.F.R. § 93.108(b) (2014) (stating that disclosure of the identity of respondents is limited on a “need to know” basis).

²⁶³ See discussion *supra* Part III.D (“Access to Relevant Information: Confidentiality and Information Dissemination Structures.”).

of what allegations were leveled against an individual in the past can help provide investigators with much needed context for their investigation.²⁶⁴ The balance between these interests is one we have struck in criminal law: the district attorneys who prosecute cases have access to a record of a defendant's arrest and charging history, regardless of the disposition of those earlier cases. This information cannot be presented to a jury and is not accessible to potential employers, but the district attorney can use it to direct an investigation, to determine what amount of bail to seek, and to shape plea offers.

The principal problem with allowing investigators to have access to records of past allegations that did not lead to a finding of misconduct is the difficulty in keeping this information confidential. The confidentiality problem is solved in the criminal justice system largely by the fact that the individuals who investigate cases are third parties without a personal interest in the case, and who are agents of the state and subject to its control. By contrast, the confidentiality concern is harder to address in the research misconduct context, where disclosing this sensitive information frequently means disclosing it to a respondent's peers and colleagues.

*E. Treating Research Misconduct
as Isolated Incidents:
The Strange Presumption
Against Patterns of Behavior*

One question on which the Federal Policy is largely silent is when and to whom an institution or agency must disclose findings from a research misconduct investigation, or act on such information received from another. For example, research misconduct investigations related to internally funded research at research institutions need not be disclosed to anybody, even if the same researcher also engages in federally funded research.²⁶⁵ Research institutions are likewise not under any obligation to provide information about the results of past misconduct

²⁶⁴ See Donna Anderson, *Scant Criminal Prosecution*, LOVEFRAUD.COM, <http://www.lovefraud.com/beware-the-sociopath/millions-of-sociopaths/scant-prosecution/> (last visited Jan. 31, 2015) (examining the difficulties in fraud prosecution).

²⁶⁵ See Wendy Wagner & David Michaels, *Equal Treatment for Regulatory Science: Extending the Controls Governing the Quality of Public Research to Private Research*, 30 AM. J. L. & MED., 119, 140 (2004).

investigations to their private research sponsors unless they privately contract to such an obligation.²⁶⁶

Likewise, when FDA becomes aware of a problem with a study that was funded by industry, it has no obligation to follow up or share its concerns with public sponsors of the same investigators. This is not to say that FDA cannot or does not look into such problems under the AIP and other frameworks, or share the results of those investigations, but it is not *required* to do so. In some ways this may make sense—FDA has limited resources and a single study is often only one data point out of many, such that the invalidation of that point does not materially affect FDA’s analysis. But the choice not to investigate a potential research misconduct instance, or to share that information with other stakeholders, comes at a cost.

The lack of communication and mutual reliance between FDA and other agencies goes both ways: even if another agency goes to the expense and trouble of investigating a research misconduct allegation and concludes that an investigator has engaged in research misconduct, FDA still has no obligation to revisit submissions based on that investigator’s work, even if it has previously relied on data implicated in the misconduct case.

While as a practical matter FDA or a funding agency may look into a suspect investigator’s prior research following a misconduct finding, it is not required as a matter of law.²⁶⁷ Rather, there is effectively a presumption that any instance of misconduct is a first-offense—a presumption that is often difficult to square with what is in the interest of public health and the integrity of the scientific record. On the institutional side, moreover, there may even be incentives to let sleeping dogs lie.

IV. THE “EASY” FIXES

A. *Expand Basic Allegation Reporting Requirements*

A basic gap in the current regulatory scheme is that there is no single database containing all relevant data on alleged and established research misconduct. There are several partial

²⁶⁶ *See id.*

²⁶⁷ *See* Pascal, *supra* note 38, at 797–98.

systems currently in place.²⁶⁸ The PHS Administrative Action Bulletin Board lists the names of individuals currently subject to administratively actions imposed by ORI, the Assistant Secretary of Health, and the Department of Health and Human Services.²⁶⁹ FDA publishes separate lists of debarred individuals and clinical investigators subject to disqualification or restrictions.²⁷⁰ The Excluded Parties List System (“EPLS”), now a part of the System for Award Management (“SAM”), provides the names of all parties excluded under government wide suspension and debarment programs.²⁷¹ The PHS ALERT system is already maintained as a confidential bank of information about individuals found to have engaged in research misconduct, including those found guilty of misconduct by their institutions, but pending ORI review:

The implementation of HHS administrative actions is monitored through the PHS ALERT, a non-public system of records that is subject to the Privacy Act. Individuals are entered into the PHS ALERT system when (1) PHS has made a finding of research misconduct concerning the individual, (2) the individual is the subject of an administrative action imposed by HHS as a result of a determination that research misconduct has occurred, (3) the individual has agreed to a voluntary corrective action as a result of an investigation of research misconduct, or (4) ORI has received a report of an investigation by an institution in which there was a finding of research misconduct concerning the individual and ORI has determined that PHS has jurisdiction.

Individuals are typically entered into the system when ORI receives an institutional investigation report in which there is a finding of research misconduct and the questioned research was supported by PHS funding. If ORI concurs with the institutional findings, the individual’s name will remain in the system until the expiration of any administrative actions imposed by PHS, at the recommendation of ORI. If ORI does not make a finding of research misconduct, the individual’s name is promptly removed from the

²⁶⁸ See *PHS Administrative Action Bulletin Board*, OFFICE OF RESEARCH INTEGRITY, <http://ori.hhs.gov/phs-admin-action-bulletin-board> (last updated Nov. 28, 2014); *FDA Debarment List (Drug Product Applications)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/default.htm> (last updated Nov. 14, 2014).

²⁶⁹ *PHS Administrative Action Board*, *supra* note 268.

²⁷⁰ See *FDA Debarment List (Drug Product Applications)*, *supra* note 268.

²⁷¹ SYS. FOR AWARD MGMT., <https://www.sam.gov> (last visited Jan. 31, 2015).

system, and the file is removed and destroyed.²⁷²

Regulators could make it mandatory for sponsors, contract research organizations, study investigators and other relevant actors to report any allegation of research misconduct along with its subsequent resolution. Although researchers may not like it, given that allegations would then be a part of their record, similar objections have not been persuasive enough to prevent mandatory reporting and record-keeping regimes in other sensitive fields, including the criminal justice system, where accused individuals frequently have a great deal more at stake than simply their reputations.

The germ of a research misconduct reporting system already exists in the Annual Report on Possible Research Misconduct that research institutions are required to file under ORI's Assurance and Compliance Program.²⁷³ Under 42 C.F.R. § 93.302, research institutions must file the report annually, and must include "information specified by ORI on the institution's compliance with [Part 93]."²⁷⁴ ORI could immediately expand the information required in this report, including the raw number of allegations received, information about the basis for rejecting allegations at the assessment and inquiry phases, data on the types of allegations made, the positions of respondents and whistleblowers, subsequent repercussions for involved parties, and so forth.

*B. Modify Confidentiality Rules
& Create an Accessible
Research Misconduct Database.*

Mandating disclosure of the content of the misconduct reporting system records to investigating bodies at institutions, potential funding agencies, private sponsors seeking investigators, and regulatory agencies would give all of these parties the information they need to make informed choices.²⁷⁵

Needless to say, permitting the disclosure of this information so broadly would raise serious confidentiality concerns, as well as create the potential for unfair prejudice against the accused. To

²⁷² 2011 ORI ANNUAL REPORT, *supra* note 109, at 19.

²⁷³ See *Assurance Program*, U.S. DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF RESEARCH INTEGRITY, <http://ori.hhs.gov/assurance-program> (last updated Jan. 8, 2014).

²⁷⁴ Institutional Compliance with Assurances, 42 C.F.R. § 93.302(b) (2014).

²⁷⁵ Titus et al., *supra* note 244, at 982.

minimize these concerns, general access could be limited to public actors like ORI and OIG, which could then serve as gatekeepers to the data subject to regulations governing the circumstances under which certain information from the database can be disclosed, and for what purposes. For example, institutional investigatory committees could be given access to certain information about past allegations against a researcher, but the use of that information could be restricted to the investigation. Legal protections could be put in place to prohibit institutions from making decisions about funding, tenure, and other issues on the basis of unsubstantiated allegations.

Another problem with broader disclosure is that it arguably is in tension with confidentiality protections in the current regulatory regime. The Federal Policy expressly says that “fair and timely procedures for responding to allegations of research misconduct” must include safeguards for both informants and subjects of allegations.²⁷⁶ Such protections are described as having several purposes. They “give individuals the confidence that their rights are protected and that the mere filing of an allegation of research misconduct against them will not bring their research to a halt or be the basis for other disciplinary or adverse action absent other compelling reasons.”²⁷⁷ In addition to various procedural protections, the policy’s confidentiality provision requires that:

To the extent possible consistent with a fair and thorough investigation and as allowed by law, knowledge about the identity of subjects and informants is limited to those who need to know.²⁷⁸

This begs the question: who “needs to know”? It ignores the reality of the scientific enterprise to think that only those investigating a particular allegation have a need for the data produced in that investigation. For the more subtle forms of misconduct in particular, willful violations may be difficult to differentiate from innocent mistakes without evidence of a pattern of the same “mistake.” Establishing this sort of pattern may only be possible by reference to past investigations that *exonerated* the subject.

Whether a more limited conception of the need to know is based on the idea that that the wrongdoing of a particular

²⁷⁶ Federal Policy on Research Misconduct, 65 Fed. Reg. 76,260, 76,263 (Dec. 6, 2000).

²⁷⁷ *Id.*

²⁷⁸ *Id.*

scientist will come out through other avenues (such as retraction of publications) or out of special solicitude for scientists' reputations, it does an ill-service to the public. To the extent this model assumes that retractions or other forms of public shaming in the scientific community can effectively identify bad actors, it also ignores the fact that many individuals accused of research misconduct will not have their name on publications or grant applications.

*C. Expand the Mandatory Use of
Data Monitoring Committees*

While institutional review boards (“IRBs”) review proposed clinical protocols and supervise ongoing trials for compliance with ethical standards, they do not provide for meaningful review of the data coming out of trials.²⁷⁹ To fill this gap, study sponsors sometimes use data monitoring committee (“DMCs”), “group[s] of individuals with pertinent expertise that review[] on a regular basis accumulating data from . . . clinical trials.”²⁸⁰ These groups are tasked with independently reviewing clinical trial data for various problems in trial conduct and analysis.²⁸¹ Though DMCs are currently required only as a means of protecting human subjects in research studies in emergency settings where informed consent is not feasible,²⁸² they are already being used more commonly in industry-sponsored research.²⁸³ FDA has attributed the increased use of DMCs to, *inter alia*: “[h]eightedened awareness within the scientific community of problems in clinical trial conduct and analysis that might lead to inaccurate and/or biased results, especially when early termination for efficacy is a possibility, and need for approaches to protect against such problems[.]”²⁸⁴ Given the demonstrated feasibility of using DMCs and their ability to introduce meaningful third-party review without disrupting the basic structure of research supervision, there’s no reason not to expand their use still further.

²⁷⁹ HUTT ET AL., *supra* note 228, at 648.

²⁸⁰ U.S. FOOD & DRUG ADMIN., GUIDANCE FOR CLINICAL TRIAL SPONSORS: ESTABLISHMENT AND OPERATION OF CLINICAL TRIAL DATA MONITORING COMMITTEES 1 (2006), *available at* [http://www.fda.gov/downloads/Regulatory Information/Guidances/ucm127073.pdf](http://www.fda.gov/downloads/Regulatory%20Information/Guidances/ucm127073.pdf) [hereinafter DMC GUIDANCE].

²⁸¹ *Id.* at 1–2.

²⁸² Exception From Informed Consent Requirements for Emergency Research, 21 C.F.R. § 50.24(a)(7)(iv) (2014).

²⁸³ HUTT ET AL., *supra* note 228, at 648.

²⁸⁴ DMC GUIDANCE, *supra* note 280, at 3.

*D. Uniform Implementation
of Best Practices*

Arguing that underreporting of research misconduct to ORI is fundamentally the result of a failure to foster a “culture of integrity” at research institutions, Titus et al. have proposed six strategies to create a culture shift.²⁸⁵ First, institutions should adopt a culture of zero tolerance by requiring reporting of all suspected misconduct, and by thoroughly and fairly investigating all allegations.²⁸⁶ Second, institutions should improve whistleblower protections.²⁸⁷ Third, institutions should establish reporting systems that clearly identify to whom allegations should be brought and clearer procedures, policies and guidelines relating to misconduct.²⁸⁸ Fourth, the institutions should train academic mentors in how to establish and maintain research rules and minimize opportunities to commit research misconduct.²⁸⁹ Fifth, institutions should use alternative means to protect the integrity of research beyond responding to formal complaints—e.g., by implementing continuing mechanisms like auditing of research records.²⁹⁰ Finally, institutional leaders should model ethical behavior.²⁹¹

These are just a few examples of ways that national implementation of best practices for institutional research misconduct policies could both reduce the incidence of misconduct and ensure a fairer process for the accused.²⁹²

One area for standardization particularly ripe for reform is whistleblower protections. The Federal Policy is inexplicably silent on the important questions of how to deal with whistleblowers who act maliciously or in bad faith and how to deal with individuals who harass whistleblowers.²⁹³ In the front-matter to the policy, OSTP responded to a comment on this subject simply by noting that “non-Federal research institutions may adopt policies to address the consequences of false, malicious, or capricious allegations and to respond to retaliation

²⁸⁵ Titus et al., *supra* note 245, at 981–82.

²⁸⁶ *Id.* at 982.

²⁸⁷ *Id.*

²⁸⁸ *Id.*

²⁸⁹ *Id.*

²⁹⁰ *Id.*

²⁹¹ *Id.*

²⁹² *Id.* at 981–82.

²⁹³ Federal Policy on Research Misconduct, 65 Fed. Reg. 76,260, 76,262 (Dec. 6, 2000).

against informants. Agencies may also address this issue in their implementation of this policy.”²⁹⁴

In a 2012 study, Dr. Donald Kornfeld, a professor of psychiatry, looked closely at 146 ORI investigations between 1992 and 2003 that resulted in a finding of misconduct.²⁹⁵ By analyzing the conduct of these respondents through a psychological lens, Kornfeld concluded that most misconduct is the result of “the interaction of psychological traits . . . and the circumstances in which these individuals found themselves.”²⁹⁶ Accordingly, Kornfeld argues that institutional policies targeted to address these psychological characteristics and circumstances are important to reducing research misconduct.²⁹⁷ This approach is akin to the “culture of integrity” argument, and it likewise highlights the importance of both (1) finding policies that work, and (2) making sure these are adopted as widely as possible.²⁹⁸ Many of Kornfeld’s prescriptions for institutions lend themselves well to generalization: improve the quality of mentoring by paying attention to the ratio of trainees to mentors and instructing mentors on how to help reduce their subordinates’ fear of failure, acknowledge the highly competitive environment of academia by providing professional counseling to help researchers deal with the pressures and psychological factors that lead to misconduct, and improve protections and incentives for whistleblowers by making sure that individuals who receive allegations have sufficient authority to assure whistleblowers of protection.²⁹⁹

One other simple adjustment Kornfeld proposes addresses the observation that research support staff are frequently “pressured

²⁹⁴ *Id.*

²⁹⁵ Kornfeld, *supra* note 21, at 877.

²⁹⁶ *Id.* at 879.

²⁹⁷ *Id.*

²⁹⁸ *Id.*

²⁹⁹ *Id.* at 880. Kornfeld also suggests that individuals who receive allegations should have the ability to resolve these allegations informally, “because individuals who are ultimately exonerated of a research misconduct charge, nonetheless can suffer detrimental consequences.” As I have argued elsewhere in this article, informal resolution of charges is problematic because it obscures the scope of the problem from regulators and funding agencies, and because institutions may have an incentive to dispose of merited cases at the margins. The problem of repairing the reputations of the falsely accused is a real one, but it is one that must be addressed by calibrating *which* parties have access to allegation information, and by implementing policies that prohibit discrimination in employment and in grant-making on the basis of unsubstantiated allegations.

to increase the intake of new subjects or to generate more data” (and indeed, that in some cases their income is tied to these metrics of productivity).³⁰⁰ Kornfeld correctly notes that eliminating financial incentives to deviate from protocol is a straightforward step every institution can and should take.

*E. Regular Audits of Misconduct
Cases Not Advanced*

A basic flaw of the Federal Policy is that it enables institutional actors with potentially conflicting motives to dispose of cases quietly early in the process of assessing allegations. A simple response to this problem would be to conduct regular audits of the allegations that are washed out of the system at the allegation assessment and inquiry stages.³⁰¹ Audits could be conducted by ORI, another HHS components (such as OIG), or by third party auditors selected by either the government or the research institution. Given the incentives and opportunity for institutions to quietly resolve allegations at these early stages (particularly those allegations made by complainants who, due to their junior status, would be unlikely to pursue the charges further), the relatively small cost of an audit regime is justifiable. Indeed, given the potential to eliminate misuse of federal research funds, it may even be financially defensible for the government to absorb the cost of these audits by considering them reimbursable direct or indirect costs.³⁰²

V. A FEW MORE RADICAL PROPOSALS

Ideally, the comparatively modest steps outlined above would (1) reveal that the problem of research misconduct is no more widespread or serious than previously thought, and (2) create sufficient additional tools for discovering and punishing misconduct so that the problem diminishes still further. What, however, might we do if these measures reveal a more pervasive

³⁰⁰ *Id.* at 878 (describing the federal process).

³⁰¹ Federal Policy on Research Misconduct, 65 Fed. Reg. 76,260, 76,263 (Dec. 6, 2000).

³⁰² As a practical matter, the costs of audits either required or approved by the agency awarding a grant are already considered allowable costs when the grantee is a domestic educational institution. See OFFICE OF MGMT. & BUDGET, CIRCULAR NO. A-21: COST PRINCIPLES FOR EDUCATIONAL INSTITUTIONS 42 (2004), http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a021/a21_2004.pdf.

and serious problem? What more radical regulatory steps might we as a society take to uproot scientific misconduct that the existing system has failed to deter or correct?

*A. An Increased Federal Role
in Conducting Investigations.*

Having the federal government conduct a greater share of the legwork in pursuing research misconduct allegations is in some sense a nuclear option: it would be an expensive government program in an era of budget austerity and would, moreover, go against a long tradition of government deference to the norms and integrity of the academy.³⁰³ Nonetheless, this option would address many of the basic weaknesses of the current system: whistleblowers would no longer be in the precarious position of having to report misconduct to peers of the accused, investigators would no longer have an incentive to protect the guilty (though the opposite could be true: professional investigators may have a reputational stake in *finding* misconduct), and the investigating agency could develop a complete database of allegations, inquiries, and investigations without running into the privacy concerns associated with sharing this information with respondents' peers.³⁰⁴

This system would create new challenges as well, by generating a more adversarial relationship between granting agencies and research institutions, and by moving the investigative role from the party that already possesses the evidence to one that would have to acquire it, often from parties with an interest in withholding it.

*B. Shift the Burden Onto Respondents
to Establish Research Integrity*

The strength of the AIP is that once the FDA invokes the policy, all of the incentives are aligned for the defendant company to do everything within its power, as quickly as possible, to demonstrate to the FDA either that the suspect data was in fact reliable or, if not, that the company has taken effective steps to remedy the problem. Unlike under the Federal

³⁰³ See discussion *supra* Part II.A (detailing the presumptive preference of institutional investigations over governmental investigations).

³⁰⁴ See CONSEQUENCES OF WHISTLEBLOWING, *supra* note 94, at 51–54 (inferring from discussion the consequences faced by whistle blowers).

Policy, where both the research institution and the respondent arguably have some incentive to play their cards close to the chest and hope that an allegation will die, the AIP puts the accused in a high stakes race to defend or repair their data.

A similar system could work for policing research misconduct in the federal grantee context. While current law allowing the federal government to recover funds supporting activities involving research misconduct and to impose conditions on future grants³⁰⁵ does encourage institutions to be proactive about investigating and punishing misconduct, these same severe penalties encourage institutions to bet on reasonable doubt sometimes, at least at the margins. A system where granting agencies presumptively initiate repayment proceedings or at least freeze payment of grant funds (either to the individual respondent or to that researcher's institutional home) based on an allegation, and where the burden is on the individual or institution to show the integrity of the research, would obviously create a stronger impetus for self-enforcement.

The problems with such a system are many. In addition to creating an opportunity for malicious or unjustified allegations, this system could prove hugely interruptive to valuable research while the researchers or institution expend time and resources trying, in many cases, to prove the negative. While some especially wealthy institutions may be able to use intramural funds to cover research while investigations are ongoing, for most institutions the immediate loss of funding would likely result in either terminating the research project or setting it back significantly. Finally, it is not clear that the factors that support such a draconian measure at the FDA-review stage (if indeed they justify it there) are present in the basic research context to which many federal dollars follow: with FDA review, there is a risk that a product whose safety is unsupported by the evidence could reach consumers, whereas the harm in many ORI cases would primarily be the damage to the research record, as well as the real and opportunity costs associated with spending federal dollars on "useless" research.

*C. Impose Greater Costs on Institutions
for the Misconduct of their Members*

A third proposal was hinted at above in the context of burden

³⁰⁵ *E.g.*, HHS Administrative Actions, 42 C.F.R. § 93.407 (2014).

shifting: rather than focus the risks of a misconduct allegation on individual researchers (as the current Federal Policy does), the respondents' home institutions could be held vicariously responsible. Such a policy would impose real costs on institutions for their members' misconduct, either by imposing additional controls on current or future federal grant dollars, or even by limiting institutions' eligibility for future funds according to their past record.

While this approach has clear flaws—it would likely exacerbate the bad incentives for institutions to hide misconduct to the same extent as it would encourage greater collaboration, and it would move the grant process away from its individual-meritocratic philosophy toward a system where the best research might be deprived of funding simply based on the conduct of a colleague within a large organization—it is worth noting that it is not without precedent. Indeed, it is similar to the phenomenon of requiring board certification in corporate integrity agreements negotiated life sciences firms by OIG,³⁰⁶ an approach meant to heighten the stakes for the individuals in the best position to ensure ongoing compliance.³⁰⁷ And although the shift away from merit-based funding determinations would be unavoidable under a “punish the institution” approach that limited future eligibility for funds, the most worrisome downsides of this approach could be largely mitigated with proper controls. For example, a safe harbor provision rewarding proactive self-reporting and self-investigation could help mitigate the incentive problem, and the penalties levied on institutions for individual incidents could be scaled based on the amount of research conducted at the institution—a “pattern” of misconduct could require more incidents at a place like Johns Hopkins University (which received 1,252 awards worth a total of over \$600 million from NIH alone in 2014³⁰⁸) than at, say, the University of South Dakota (which received 9 NIH awards worth a total of just under \$6 million³⁰⁹).

³⁰⁶ See Katrice B. Copeland, *Enforcing Integrity*, 87 IND. L.J. 1033, 1050–52 (2012).

³⁰⁷ *Id.*

³⁰⁸ *Johns Hopkins University: Awards Summary for Fiscal Year 2014*, NAT'L INST. OF HEALTH, <http://report.nih.gov/award/index.cfm?ot=&fy=2014&state=&ic=&fm=&orgid=4134401&distr=&rfa=&om=n&pid=&view=state> (last updated Dec. 8, 2014).

³⁰⁹ *University of South Dakota: Awards Summary for Fiscal Year 2014*, NAT'L INST. OF HEALTH, <http://report.nih.gov/award/index.cfm?ot=&fy=2014&state=&ic>

VI. CONCLUSION

The federal government expends billions of dollars each year funding scientific research, yet the system in place for monitoring and preventing misconduct in the use of those funds fails to even provide sufficient data to identify the scope of the problem. The system, built on deference to the academy, its norms, and the basic integrity of its members, creates substantial opportunities for unchecked misconduct. If we acknowledge that researchers are subject to various incentives to engage in misconduct, and that potentially widespread misconduct in the scientific arena has substantial direct and indirect costs, then we should reconsider how we police this misconduct. At the very least, we should implement changes designed to shed more light on the scope of the problem, require research institutions to adopt recognized best practices in encouraging a culture of integrity and compliance, and use low-cost tools like data monitoring committees, external audits, and greater information sharing to make identifying and investigating misconduct more effective. If these measures prove inadequate, we must consider making more radical changes to the federal framework for addressing research misconduct.