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ILLUSORY PROTECTIONS FOR THOSE ACCUSED OF SCIENTIFIC RESEARCH MISCONDUCT: NEED FOR REFORM

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I. INTRODUCTION

It is well established that scientific research misconduct often goes unreported.[1] Consequently, such conduct may be more prevalent than otherwise expected in a professional community that counts on—and prides itself on—self-regulation. In the last few decades, concerns about scientific research integrity have gravitated to center stage,[2] stimulating the introduction and revisions of federal regulations and institution rules. Perhaps most important to biomedical research are U.S. Department of Health and Human Services (HHS) regulations, in effect since 2005 (42 C.F.R. Part 90). These federal regulations dictate activity by HHS, agencies of the U.S. Public Health Service (PHS), including the National Institutes of Health (NIH), as well as thousands of

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1. Sandra L. Titus et al., *Repairing Research Integrity*, 453 NATURE, 980-82 (2008) (indicating that not all potential misconduct are reported to universities and few are reported to ORI).

2. In 1985, Congress enacted the Health Research Extension Act, requiring that PHS-funded institutions establish a process for evaluating reports of scientific fraud. In March 1989, the PHS created the Office of Scientific Integrity (OSI) at NIH, and an Office of Scientific Integrity Review (OSIR) within HHS. In June 1992, these offices were merged to create the Office of Research Integrity (ORI), an entity not part of NIH. Press Release, U.S. Dep't of Health and Human Services, Fact Sheet: Promoting Integrity in Research (Jan. 13, 2010), http://www.hhs.gov/news/factsheet/integrity.html [hereinafter Promoting Integrity in Research].

institutions receiving research funds from PHS agencies. HHS regulations serve as models for regulations and resulting institutional rules/policies affecting all science communities on the issue of research misconduct.

In an apparent effort to motivate people to report suspected research misconduct, regulations and institutional rules have provided increasingly broad protections for "whistleblowers" (complainants). Such regulations and rules prohibit, for example, retaliation against whistleblowers. Even today, the federal government's Office of Research Integrity (ORI) and other groups continue to advocate for even greater protections for whistleblowers, as well as "zero tolerance" both for those who commit misconduct and for those who fail to report suspected misconduct.[3] Regulations and rules also protect research institutions themselves against retaliation and lawsuits "to conserve public funds."[4]

These regulations and rules appear to be motivated by a belief that if costs to the whistleblower and the institution are kept low, good faith researchers will report research misconduct whenever possible. Despite significant protections for whistleblowers and institutions, however, many scientists remain reluctant to come forward. Even the repeated broadening of these protections has not provided the necessary motivation.

In contrast to whistleblowers, protections for those accused of misconduct have not garnered much attention. In fact, legal protections for accused scientists are few and far between, and often entirely ineffective. Furthermore, little to no recourse exists when protections for the accused fail to provide anything remotely resembling due process.

Despite a lack of public attention on the issue, the dearth of proper protections for those accused is likely to be a significant part of why those people having legitimate concerns do not volunteer information. Without viable protections in place for accused researchers, well-meaning scientists will be reluctant to come forward. Most scientists understand the significant harm associated with even a mere allegation of misconduct, not to mention the cost of an official proceeding, regardless of any proof or outcome. Confidentiality failures, for example, cause immediate damage, while at the same time a lack of procedural protections makes it difficult for researchers to defend themselves against an institution acting as an investigator, judge and jury. Scientists generally have no interest in harming a fellow

3. *See, e.g.*, Titus et al., *supra* note 1, at 980, 982.

4. 42 C.F.R. § 93.107 (2011) (stating that the regulations must be interpreted, *inter alia*, "to conserve public funds").

researcher's reputation and career (not to mention causing harm to other affiliated people) unless they have either definitive proof of the most egregious misconduct, or a malicious motive in coming forward.

If scientific communities wish to promote scrutiny of research misconduct, and thereby root out and reduce such conduct, federal regulations and institutional rules must enact and enforce adequate and equitable protections for *all* scientists, not just political favorites. In other words, such scientists necessarily include those accused of misconduct—even the guilty—not just whistleblowers and others involved in the process. Such protections must be in place well before a formal allegation is lodged. In addition, after official proceedings begin, protections must remain in place continuously throughout the process, and extend through a viable and objective appeals process. Such protections will motivate researchers to come forward with information regarding suspicious activity. A need for reform exists to achieve the dual goals of maintaining zero tolerance of misconduct and appropriately protecting all scientists. Proposed changes to federal regulations, such as those described below, will go far to help achieve these goals.

II. RESEARCHERS ACCUSED OF MISCONDUCT CURRENTLY LACK MANY IMPORTANT PROTECTIONS

Federal regulations outline responsibilities and protections for those involved in scientific research misconduct allegations and proceedings. HHS regulations describe, for example, official proceedings involving: (1) an initial assessment to determine whether an allegation meets the definition of research misconduct;[5] (2) an institutional inquiry to determine whether to conduct an investigation;[6] and (3) an institutional investigation.[7] Individuals involved in the proceedings usually include the accused (respondents), complainants, witnesses, inquiry and investigation committee members, as well as other scientists, administrators and legal members of the institution needed to implement the process. Notably, regulations today fail to provide the accused with the same level of protections given to everyone else in the process.

For instance, 42 C.F.R. § 93.300 (2011) describes overall protections that institutions must put in place, describing the "[g]eneral responsibilities for compliance" of the regulations as a whole. While certain portions of this section refer to protections such as prompt

5. 42 C.F.R. § 93.307(a) (2011) ("institutional inquiry").
6. *Id.* § 93.307(c).
7. *Id.* § 93.310 ("institutional investigation").

action, confidentiality and fairness in proceedings,[8] subsection (d) addresses the protection of "positions and reputations" of scientists involved in the process.[9] Specifically, subsection (d) states that institutions must "[t]ake all reasonable and practical steps to protect the positions and reputations of good faith complainants, witnesses and committee members and protect them from retaliation by respondents and other institutional members."[10] As intended by the drafters, this subsection fails to mention respondents (the accused), but instead only protects others from retaliation by respondents.[11]

As stated in the relevant final rules:

> The purpose of the retaliation provision is to encourage researchers to come forward with good faith allegations of research misconduct and to encourage good faith cooperation with a research misconduct proceeding. *In ORI's experience, there has been no showing of a need to protect respondents from retaliation in order to ensure they will take steps to defend against an allegation of misconduct.* In contrast, experience has shown a need to restore the reputations of respondents where there is a finding of no misconduct and Sec. 93.304(k) requires institutions to do that. *If a need to protect respondents from retaliation is shown, institutions have broad discretion under the rule to address that situation on a case-by-case basis or adopt a policy to remedy the problem.*[12]

In other words, regulations appear to assume that such protections are entirely unnecessary for an accused scientist unless and until there is an affirmative finding of no misconduct, i.e., only after all relevant proceedings, in their entirety are finished. The stated reason is that accused scientists "will take steps to defend against an allegation of misconduct."[13]

While accused scientists will certainly take steps to defend themselves, they nearly always suffer immediate and long-term consequences created by the mere existence of an accusation. These adverse effects often last for the entire length of misconduct proceedings, which can take years to complete. In addition, adverse

8. *Id.* § 93.300(b), (c), (e).

9. *Id.* § 93.300(d).

10. *Id.*

11. *Id.*; *see also id.* § 93.304(l) (2011) (citing similar protections, but failing to provide protections for respondents); *id.* § 93.226 (2011) (defining "Retaliation" without mentioning respondents).

12. Public Health Service Policies on Research Misconduct, 70 Fed. Reg. 28370, 28377-78 (May 17, 2005) (to be codified at 42 C.F.R. pts. 50, 93) (emphasis added).

13. *Id.* at 28378.

effects often endure after proceedings conclude, even when no misconduct is found.[14] One-sided protections, therefore, do not encourage good faith researchers to come forward and cooperate in misconduct proceedings. The inherent lack of fairness and proper protection for the accused creates a belief that misconduct allegations and procedures—baseless or not—impose a draconian penalty upon the accused. This belief "chills" the very researchers whom the regulations intend to encourage to come forward.

Although the Federal Register states that "institutions have broad discretion under the rule to address that situation on a case-by-case basis or adopt a policy to [protect the accused from retaliation],"[15] most institutions choose not to provide additional protections for accused scientists in this regard, or in fact, in any other regard, outside those mandated by federal regulations and/or already existing institutional rules. At minimum, the significant effort involved in drafting such "discretionary" rules create an incentive for institutions to take the passive route, that is, do nothing to protect accused scientists beyond the legally-mandated minimum. One clear example is seen in a recent case at Harvard University. As noted in a *New York Times* article, "[u]nder Harvard's faculty policy, the university cannot make known its evidence against [the accused], nor can he defend himself, until the government's report is ready."[16]

Another example of an obvious discrepancy in the regulations relates to possible recourse against bad faith allegations. As stated in the Federal Register, finalizing current regulations:

> The final rule, Sec. 93.300(d), requires institutions to take all reasonable and practical steps to protect the positions and reputations of good faith complainants and protect them from retaliation by respondents and other institutional members. *By negative implication, such steps are not required for bad faith complainants.* Bad faith complainants are those who, under the definition of "good faith" in Sec. 93.210, do not have a belief in the truth of their allegation that a reasonable person in the complainant's position could have based on the information known to the complainant at the time. *We have determined there is no need for the final rule to further address bad faith allegations, given that institutions may have internal standards of*

14. *Cf.* Nicholas Wade, *Difficulties in Defining Errors in Case Against Harvard Researcher*, N.Y. TIMES, Oct. 25, 2010, *available at* http://www.nytimes.com/2010/10/26/science/26hauser.html.

15. Public Health Service Policies on Research Misconduct, 70 Fed. Reg. 28370, 28377-78 (May 17, 2005) (to be codified at 42 C.F.R. pts. 50, 93) (emphasis added).

16. *See, e.g.*, Wade, *supra* note 14.

conduct that address matters not addressed in the final rule (Sec. 93.319).[17]

In other words, federal regulations currently fail to provide *any* protection for scientists against bad faith accusations, while at the same time exacting serious consequences to any alleged "bad faith" by an accused scientist. Because many institutions do not go beyond the regulations' mandates, an accused scientist frequently has no remedy against bad faith allegations.

Following current political trends, as well as reasoning behind current federal regulations, most agencies and institutions bend over backwards to provide rules that protect complainants and the institution itself, but not accused scientists. Most institutions provide accused scientists barebones protections at best, which often do not work at all.

III. EXISTING PROTECTIONS FOR ACCUSED SCIENTISTS ARE INSUFFICIENT

On its website, HHS states that research misconduct regulations aim to provide "protection for respondents and complainants in research misconduct cases. Institutions are required to protect the confidentiality of the individuals involved, including the respondent."[18]

It is technically correct that some legal protections currently exist for accused scientists, at least in theory. According to HHS federal regulations and some agency/institutional rules, for example, an institution must afford: (1) procedures that provide prompt response and resolution of allegations; (2) confidentiality of the identity of parties involved; and (3) fairness to ensure an impartial and unbiased proceeding.[19] With regard to the issue of fairness, regulations allow respondents certain involvement in the evaluation process itself, such as the ability to respond to draft inquiry and investigation reports, and the ability to review some evidence.[20] Such protections are, at best, scant protection needed for anyone accused. Furthermore, if an institution fails to implement these minimal protections properly, it is unclear how an accused researcher may remedy the situation.

For example, federal regulations mandate that institutions provide

17. Public Health Service Policies on Research Misconduct, 70 Fed. Reg. 28370, at 28379-80 (emphasis added).

18. Promoting Integrity in Research, *supra* note 2.

19. *See* 42 C.F.R. § 93.300 ("General responsibilities for compliance"); *id.* § 93.108 (2011) ("Confidentiality"); *id.* § 93.210 (2011) (defining "Good faith"); *see also* NAT'L INST. OF HEALTH NIH INTRAMURAL RESEARCH PROGRAM POLICIES & PROCEDURES FOR INVESTIGATING SCIENTIFIC MISCONDUCT (2001), http://sourcebook.od.nih.gov/ethic-conduct/smpolicy.htm.

20. Promoting Integrity in Research, *supra* note 2.

prompt action and resolution of any allegation of research misconduct.[21] Action and resolution may involve: an inquiry, an investigation, and an institutional appeal, if available.[22] As noted by NIH, a "prompt response to an allegation helps to minimize any harm to the public that could result if misconduct is found and allows those who are incorrectly accused to clear their names without going through a long process."[23] According to HHS regulations, the entire procedure at an institution for addressing and making a finding regarding allegations of research misconduct, including any institutional appeal, is intended to take less than a year, and even less time if no appeal process is available.[24] As stated in the regulations, final resolution within this time frame is a necessary part of "[a] thorough, competent, objective, and fair response to allegations of research misconduct."[25]

Published decisions of the HHS Departmental Appeals Board (DAB), however, show that misconduct cases often take many years to conclude at a given institution.[26] For example, the *Imanishi-Kari* case involved a scientist eventually exonerated by the DAB regarding allegations of misconduct relating to work reported in a *Cell* paper.[27] The dispute began with concerns raised by scientists in May 1986.[28] After initially concluding that no misconduct took place, NIH reopened

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21. 42 C.F.R. § 93.300(c).

22. *See id.* §§ 93.212, 93.307, 93.310.

23. NAT'L INST. OF HEALTH, A GUIDE TO THE HANDLING OF SCIENTIFIC MISCONDUCT ALLEGATIONS IN THE INTRAMURAL RESEARCH PROGRAM AT THE NIH (2001), http://sourcebook.od.nih.gov/resethicscases/nih%20misconduct2.pdf (last visited Mar. 13, 2011).

24. An institution must complete an inquiry within 60 days of its initiation "unless circumstances clearly warrant a longer period." 42 C.F.R. § 93.307(g) (2011). If an inquiry determines that an investigation is warranted, the institution must begin its investigation within 30 days of that determination. 42 C.F.R. § 93.310(a) (2011). An institution also "must complete all aspects of an investigation within 120 days of beginning it," including sending a final report to ORI. 42 C.F.R. § 93.311 (2011). Assuming the institution's procedures provide for an appeal by respondents (not required), the institution must complete that appeal within 120 days of its filing. 42 C.F.R. § 93.314 (2011). Regarding these two 120-day time periods, an institution must ask ORI for any extension in writing if unable to meet deadlines. §§ 93.311 and 93.314.

25. 42 C.F.R. § 93.304(b) (2011).

26. Popovic v. United States, 997 F. Supp. 672, 675 (D.Md. 1998) (allegations raised in November 1989, formal investigation initiated by NIH in October 1990, revised report forwarded to OSIR in March 1992, final report issued in December 1992); *Angelides*, DAB Decision No. 1677, 1999 WL 88783 (H.H.S. Feb. 5, 1999), at *7 (allegations raised in December 1992, final institutional investigation report issued in September 1994, an institutional appeal occurred thereafter, resulting in ORI charges filed in Mar. 1997); *Sharma*, DAB Decision No. 1431, 1993 WL 742551 (H.H.S. Aug. 6, 1993), at *5 (stating OSI/OSIR issued a decision nearly two years after beginning its investigation).

27. *Imanishi-Kari*, DAB Decision No. 1582, 1996 WL 399931 (H.H.S. June 21, 1996), at *2.

28. *Id.* at *5.

an investigation in May 1989, which the ORI eventually conducted.[29] In October 1994, the ORI issued a report concluding that research misconduct occurred.[30] In November 1994, the accused scientist requested a hearing with the DAB regarding ORI's charges.[31] The DAB issued its decision finding no research misconduct on June 21, 1996.[32] In other words, from start to finish, this case went on for a *decade*, involving activity spanning years at any one institution or agency.

Likewise, in the more recent Harvard case, as noted by the *New York Times*, "[t]he still unresolved case of Marc Hauser, the researcher accused by Harvard of scientific misconduct, points to the painful slowness of the government-university procedure for resolving such charges."[33] In this case, "Harvard's investigation . . . has stuck so closely to the letter of government-approved rules for investigating misconduct that the process has become unduly protracted—it lasted three years—and procedurally unfair to the accused."[34] Thus, while the process is supposed to be short in theory, in reality, it is a painfully long process in many instances, especially if it relates to high profile work.

Another basic protection for researchers, at least in theory, is that institutions must keep the identity of respondents (accused) as well as complainants (whistleblowers) confidential in research misconduct proceedings. In this regard, 42 C.F.R. § 93.108(a) (2011) states that "[d]isclosure of the identity of respondents and complainants in research misconduct proceedings is limited, *to the extent possible, to those who need to know*, consistent with a thorough, competent, objective and fair research misconduct proceeding."[35] Questions leap to mind upon reading this regulation, such as: what is "*to the extent possible*" and who exactly "*needs to know*"? At minimum, the "need to know" group will include every party to the assessment, inquiry and investigation at the institution in question, including every witness questioned, those in charge of handling allegations (including administrators), every person on any inquiry and investigation committee, any scientific, IT and forensic experts used, and legal personnel. In other words, the "need to know" group will likely be large in any given case.

The unfortunate reality is that damaging gossip easily flies when so many individuals have access to "tantalizing" information, with little to no accountability. Considering this fact, how does an institution effectively enforce confidentiality? How does an institution monitor,

29. *Id.* at *5-6.
30. *Id.* at *6.
31. *Id.*
32. *Id.* at *1.
33. Wade, *supra* note 14, at 1.
34. *Id.*
35. 42 C.F.R. § 93.108(a) (2011) (emphasis added).

control, or even hold accountable so many people directly, much less those who may have heard information from them? Federal regulations and the vast majority of institutional rules completely fail to address these crucial questions, or even take a stab at providing viable answers.

In addition to prompt action and confidentiality, federal regulations also require that institutions respond to allegations "in a thorough, competent, objective and fair manner."[36] As part of this requirement, regulations allow respondents to respond to draft inquiry and investigation reports, and to review some evidence.[37] Notably, however, institutions are not required to provide respondents access to any evidence considered in an inquiry.[38] In other words, respondents have no recourse if an inquiry committee selectively considers evidence in the most damaging way. Moreover institutions need only provide access to "evidence upon which the report is based" in an investigation.[39] Even at the investigation stage, respondents only have access to evidence on which an investigation report is based. Respondents have no right to review any evidence not mentioned in the investigation report, even if exculpatory evidence is missed, misinterpreted, or ignored during the proceedings.[40]

It is clear to anyone affected by allegations of research misconduct that, at minimum, confidentiality, prompt action and resolution and fairness in procedure are absolutely critical. As noted by NIH, "[a]llegations of misconduct that prove to be untrue, even if they were made in good faith, can damage careers and have a chilling effect on research."[41]

Assuming an institution fails to provide these minimal protections, however, what exactly can one do about it? According to regulations and many institutional rules, not much. HHS regulations do not currently provide recourse if an institution fails to meet minimal mandated standards of care. At most, a researcher may be able to appeal to the institution itself to rectify the situation (assuming the institution allows it and rectifying the situation is possible). *In other words, at best, researchers must rely on the very institution that failed to provide protections in the first place.* In fact, it appears that no formal appeal process exists at many universities, NIH, and other federal institutions or agencies.

As such, if an institution makes a questionable finding of research

36. *Id.* § 93.300(b).

37. *Id.* § 93.304 (2011).

38. *Id.* § 93.308 (2011).

39. *Id.* § 93.312(a) (2011).

40. Public Health Service Policies on Research Misconduct, 70 Fed. Reg. 28370, at 28373.

41. NAT'L INST. OF HEALTH, *supra* note 23, at 1.

misconduct, for example, based on dubious evidence, bias of guilt or personal grudge, or even a mistake, is there any recourse for affected scientists? One must consider that federal regulations have set up misconduct proceedings to be adversarial; that is, it is the accused researcher versus the investigating institution and the people it chooses to represent it. Especially after spending significant time and money to "prove" its case, institutions often have a vested interest in making a negative finding in order to justify bringing the case in the first instance, and to show "zero tolerance" for misconduct in a global sense.

Moreover, an institution can easily make negative findings in light of, for example: (1) the institution's low burden to prove research misconduct, that is, a preponderance of the evidence; (2) the fact that the definition of research misconduct includes conduct committed "recklessly," not just "intentionally" or "knowingly"; and (3) respondents have the burden to prove affirmative defenses, such as good faith or difference of opinion. Thus, accused scientists sit in the dangerous position of being investigated, evaluated, and judged by the same entity, often involving many of the same people throughout the process, where an institution can easily make a devastating finding.

Notably, HHS regulations do not require that an institution provide any kind of appeal process, much less an objective one, after the institution makes an adverse determination.[42] At first blush, HHS regulations appear somewhat misleading on this point because a relatively sophisticated appeal process does exist regarding an ORI adverse decision. Notably, however, the ORI differs from an institution itself where the alleged misconduct takes place.

One might think a researcher can "appeal" a purely institutional determination to the ORI, but this is not the case. As it turns out, regardless of what the ORI ultimately decides to do (and even if it determines that no research misconduct took place), once an institution makes a finding of research misconduct on its own, that finding, and any imposed sanctions, can stand on a permanent basis. Researchers may have no avenue, via the ORI or any other agency, to initiate an objective review of an institution's adverse decision, or to otherwise "reverse" the decision or institutional sanctions. At best, researchers can attempt to file a complaint with a court after "final agency action."[43] Because U.S. agency laws impose significant limits on causes of action and impose high burdens of proof on plaintiffs, however, such cases are likely to be costly, difficult to bring and ultimately unsuccessful.[44]

42. *See* 42 C.F.R. § 93.314 (2011) (stating that institutional appeals are "not required").

43. *See id.* § 93.500 (2011).

44. Judicial review of final agency actions is governed by the Administrative Procedure Act (APA). 5 U.S.C. § 706 (2011). Under the APA, a reviewing court may set aside agency actions, findings, or conclusions only if they are arbitrary, capricious, an abuse of discretion, or

Moreover, many believe courts are generally unsuited to resolve research misconduct cases in any event.[45]

IV. PROPOSALS FOR REFORM

Damage associated with allegations of research misconduct presents itself in the form of: loss in reputation, loss in time and resources for research, personal stress, reduction in quality of life, and over-scrutiny of research and manuscripts. Further damage may also include a reduction in publication rates, research grant awards, professional advancement, academic tenure, promotions, admission to scientific or honor societies, and social status. This type of damage often happens after a misconduct proceeding begins, but well before any official finding occurs. Moreover, the damage can be permanent regardless of ultimate outcome. Even assuming an institution makes "all reasonable and practical efforts" to restore the reputation of an accused scientist after the institution has made no finding of research misconduct,[46] such efforts are likely be too little too late.

HHS can modify existing federal regulations to provide adequate protections for accused researchers. Ten proposals for reform, presented below, provide guidance.

Proposal 1: Enact regulations mandating that an institution provide respondents copies of, or supervised access to, all evidence considered during an inquiry or investigation.

Rationale: Respondents should have access to all available evidence in order to adequately avail themselves to exculpatory evidence that might otherwise be missed or ignored.

Proposal 2: Enact regulations requiring that an inquiry consider and address in a report all raised affirmative defenses, such as evidence of good faith, differences of opinion and/or honest error before making a determination to go forward with an investigation.

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otherwise not in accordance with the law. 5 U.S.C. § 706(2) (2011). This constitutes a high threshold to meet, and a party challenging an agency's action as arbitrary and capricious bears the burden of proof. City of Olmsted Falls v. Fed. Aviation Admin., 292 F.3d 261, 271 (D.C. Cir. 2002) (citations omitted).

45. *See, e.g.*, Luckey v. Baxter Healthcare Corp., 2 F. Supp. 2d 1034, 1047 (N.D. Ill. 1998) (noting that "the legal process is not suited to resolving scientific disputes or identifying scientific misconduct") (quoting United States ex rel. Milam v. Regents of Univ. of Cal., 912 F. Supp. 868, 886 (D. Md. 1995)); *see also* Dan L. Burk, *Research Misconduct: Deviance, Due Process, and the Disestablishment of Science*, 3 GEO. MASON INDEP. L. REV. 305, 333-34 (1995).

46. *See* 42 C.F.R. § 93.304(k) (2011).

Rationale: To the extent that allegations and evidence are insufficient and/or evidence establishes good faith, difference of opinion or honest error, the process should stop at an inquiry. Proper consideration at an inquiry will reduce the time researchers and institutions are subjected to costs associated with allegations and misconduct proceedings.

Proposal 3: Enact regulations that clearly define "recklessly" in the definition of research misconduct.[47] The definition should require an *intent* to deceive or a *conscious* reckless disregard for the truth. Mere negligence should not meet this standard, however egregious.

Rationale: Because regulations and published decisions do not clearly characterize "recklessly" in the definition of research misconduct, this prong could be used to make inappropriate findings of research misconduct. Equating wrong or sloppy science with research misconduct will "chill" scientists, research, as well as public dissemination of science. Avenues already exist to identify and correct erroneous science.

Proposal 4: Enact regulations mandating that "significant departure" and "accepted practices" in the definition of research misconduct be defined by objective outside experts in the field, and in light of published evidence, rather than based on opinion of individuals directly involved in the misconduct proceeding.[48]

Rationale: Regulations and published decisions do not clearly characterize "significant departure from accepted practices" in the definition of research misconduct. Absent an objective means for defining "significant departure" and "accepted practices," an institution could inadvertently make an adverse finding based what amounts to a difference of opinion, which is not research misconduct.[49] Reasonable minds often differ on what "significant departure" means, and this can go to the heart of a research misconduct case.

Proposal 5: Enact regulations mandating that violations of confidentiality regarding identity of respondents constitute research misconduct, subject to allegation, inquiry, investigation, and sanctions.

Rationale: Confidentiality is a critical protection for accused researchers, and one that is often violated without accountability or

47. *Id.* § 93.104(b) (2011) (requiring that a finding of research misconduct requires that the "misconduct be committed intentionally, knowingly, or recklessly").

48. *See id.* § 93.104(a) (stating that a finding of research misconduct requires that there "be a significant departure from accepted practices of the relevant research community").

49. *See id.* § 93.103(d) (2011) (stating that "[r]esearch misconduct does not include honest error or differences of opinion").

recourse.

Proposal 6: Enact regulations outlining that lodging a bad faith allegation constitutes research misconduct, and/or otherwise triggers an objective review, finding and consequences.

Rationale: Regulations provide no recourse against abuse by bad faith actors intent on damaging others out of malice or for personal gain.

Proposal 7: Enact regulations requiring that an institution/agency prove research misconduct by clear and convincing evidence (CCE), especially before imposing any sanctions or publicizing a negative finding. The CCE burden is higher than preponderance of the evidence (POE), but less than "beyond a reasonable doubt."

Rationale: A determination of research misconduct can demoralize scientists, reduce funding, publication and promotion, and even destroy careers. The cost is often more devastating than a financial or business loss in a court proceeding. One presumes researchers are good actors until proven otherwise.

Proposal 8: Revise regulations to reflect that respondents/accused receive the same "positions and reputation" protections as complainants until, and unless, the institution makes a final determination of research misconduct, and after appeals have been exhausted.

Rationale: Respondents are often damaged by an allegation before a formal finding is made. For example, confidentiality is easily breached, but it is often difficult to identify a breaching party.

Proposal 9: Enact regulations requiring that ORI (or other objective outside agency) enforce the mandated timelines, with consequences to the institution or agency if timelines are not met, e.g., outside agency will take over and/or stop proceedings permanently.

Rationale: Regulations currently provide timelines. Damage and losses resulting from allegations and misconduct proceedings often occur well before any formal proceeding concludes. Delay in concluding matters inappropriately exacerbates such losses.

Proposal 10: Enact regulations mandating that ORI (or other objective outside agency) has authority to reverse or alter findings and sanctions by an institution or agency.

Rationale: Researchers accused of misconduct are investigated, evaluated and judged by an institution that can easily make a devastating finding. Regulations provide no accountability or recourse against factually or legally wrong conclusions or overzealous sanctions.

Creating and enforcing equitable protections for those who are accused of research misconduct will provide much needed fairness to the process of evaluating such allegations. Moreover, additional protections may actually motivate good faith researchers to come forward with information regarding misconduct. While providing whistleblower protection is important, it has proven ineffective by itself. In a political environment advocating for "zero tolerance" for those who commit research misconduct, as well as those who fail to report suspected misconduct, protections against overzealousness and abuse are prudent. Doing so will help promote the very ideals of research integrity that scientific communities wish to accomplish.