

THE OFFICE OF RESEARCH INTEGRITY: EXPERIENCE AND AUTHORITIES

*Chris B. Pascal**

I. INTRODUCTION

The Office of Research Integrity (“ORI”) is a statutory office created by Congress in 1993,¹ for which authority to respond to allegations of “misconduct in science” originally arose under an earlier federal regulation.² Under the 1993 legislation, the key requirements for ORI are: responding to allegations of research misconduct, defining research misconduct, and overseeing inquiries and investigations of research misconduct initiated by research institutions that receive Public Health Service (“PHS”) funds or apply for such funds.³ In addition, the statute specifically requires ORI to establish administrative processes and standards for protecting whistleblowers who act in “good faith.”⁴

ORI has implemented the requirement to protect whistleblowers, using the term “complainants” in the regulation, by adding specific requirements to the “Public Health Service Policies on Research Misconduct” (“PHS regulation”), promulgated May 17, 2005.⁵ In § 93.210 of the PHS regulation, ORI has defined “good faith” in reporting allegations of research misconduct “as applied to a complainant or witness” to mean “having a belief in the truth of one’s allegation or testimony that a reasonable person in the complainant’s or witness’s position could have based on the information known to the complainant or witness at the time.”⁶

* B.A., Auburn University (1971); J.D., Duke University of Law (1974). The opinions expressed herein are those of the author and do not necessarily represent the views of the Office of Research Integrity, the U.S. Department of Health and Human Services, or any other federal agency.

1. National Institutes of Health Revitalization Act of 1993, Pub. L. No. 103-43, § 161, 107 Stat. 122, 140-41 (codified as amended at 42 U.S.C. § 289b (2000)).

2. Responsibility of PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science, 54 Fed. Reg. 32,449 (Aug. 8, 1989) (codified at 42 C.F.R. §§ 50.101-105 (2004)). In 2005, the Department of Health and Human Services promulgated a final rule removing 42 C.F.R. pt. 50, with the authority and functions of the ORI relocated to “a new more comprehensive part” at 42 C.F.R. pt. 93. Public Health Policies on Research Misconduct, 70 Fed. Reg. 28,370, 28,370, 28,384-85 (May 17, 2005) (codified at 42 C.F.R. §§ 93.400-.413 (2007)).

3. 42 U.S.C. § 289b(a)(3)(A), (c).

4. *Id.* § 289b(e).

5. *See, e.g.*, 42 C.F.R. § 93.108 (limiting the “disclosure of the identity of respondents and complainants in research misconduct proceedings”).

6. 42 C.F.R. § 93.210.

In addition, the PHS regulation imposes responsibilities on research institutions to protect good faith complainants, witnesses and committee members who participate in conducting inquiries and investigations of misconduct. Under § 93.300(d), the institution is required to “[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.”⁷ Moreover, § 93.300(e) requires institutions to provide confidentiality “to all respondents, complainants, and research subjects identifiable from research records or evidence.”⁸ This requirement for confidentiality is critical to a fair and competent process for respondents, complainants, and other involved parties. Without protections for confidentiality, the complainant would be at increased risk of retaliation and the respondent’s reputation for honesty would be seriously jeopardized even if the allegation was disproved. Both of these outcomes would undermine the trust and fairness of the process.

II. RESEARCH MISCONDUCT: A PRELIMINARY OVERVIEW

A. *Defining Research Misconduct*

In the PHS regulation, research misconduct is defined as:

fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- (a) Fabrication is making up data or results and recording or reporting them.
- (b) 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.
- (c) Plagiarism is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.
- (d) Research misconduct does not include honest error or differences of opinion.⁹

In order to make a finding of research misconduct, the institution or ORI must find that there was a “significant departure from accepted practices of the relevant research community;” that the misconduct was “committed intentionally, knowingly, or recklessly;” and that “[t]he

7. *Id.* § 93.300(d).

8. *Id.* § 93.300(e).

9. *Id.* § 93.103.

allegation [was] proven by a preponderance of the evidence.”¹⁰ The institution or ORI has the burden of proof for finding research misconduct.¹¹ While honest error or honest difference of opinion can negate a finding of research misconduct, the “respondent has the burden of going forward with and proving, by a preponderance of the evidence,” that honest error or honest difference of opinion occurred.¹²

B. Limits to ORI Jurisdiction

In addition to the formal research misconduct contemplated under the PHS regulation, there are a number of other questionable or irregular research practices that diminish the accuracy and reliability of the research processes and outcomes. These include bias in interpreting and reporting research data, such as dropping data points without a legitimate scientific justification, inadequate recordkeeping, failure to report data that contradicts one’s own research, and publishing the same data multiple times that may mislead others into believing that the significance of the data is greater than deserved. These actions would not constitute research misconduct under the PHS regulation unless the action was intentional, knowing, or reckless and, therefore, constituted fabrication or falsification.

Bias can also occur when the “best” experiment is published rather than a representative result. Similarly, biased reporting occurs when a clinical trial is carried out with inadequate statistical power and it is reported that the experimental treatment was unsuccessful. In fact, if additional subjects were used in the study, the statistical power would be greater and might demonstrate that the experimental treatment was actually successful.

ORI jurisdiction is limited to allegations of misconduct where the research is supported by PHS funds or there is an application for PHS funds.¹³ In contrast, research institutions have no such limitation. For example, if Johns Hopkins School of Medicine received an allegation of misconduct against a Principal Investigator (“PI”), who was supported by private funds, state funds, or a grant from a non-federal source, it would have plenary authority to investigate and take actions against the PI under its own authority as employer and manager of the research institution, assuming that it has the appropriate institutional policies in

10. *Id.* § 93.104.

11. *Id.* § 93.106(b)(1).

12. *Id.* § 93.106(b)(2)-(3).

13. *Id.* § 93.102(a).

place,¹⁴ which many large institutions do.

ORI has no jurisdiction over misconduct allegations that involve private funding, state funding, or other sources such as a foundation or a non-profit that supports research.¹⁵ ORI also does not have misconduct jurisdiction over falsification or fabrication of research that involves the regulatory authority of the Food and Drug Administration, such as new drug applications.¹⁶ However, there are misconduct cases where there could be joint jurisdiction by ORI and the FDA, such as when there is both PHS funding and FDA regulatory authority over a pending new drug application where misconduct is alleged. In addition, ORI has jurisdiction over research misconduct that is alleged in the FDA intramural research program since that research is supported with PHS funds.¹⁷

C. Federal-wide Policy on Research Misconduct

The Department of Health and Human Services (“HHS”), acting through ORI, is not the only entity that responds to research misconduct. In 2000, under the auspices of the White House Office of Science and Technology Policy (“OSTP”), a federal-wide policy on research misconduct was adopted following a Federal Register announcement, receipt of public comments, and final publication of the federal-wide policy.¹⁸ The general framework for federal agency management of research misconduct was the result of this process. Approximately sixteen science agencies were involved in the OSTP process, including HHS, the National Science Foundation (“NSF”), the Department of Veteran Affairs, the Department of Energy, and many others.¹⁹ HHS (through ORI) and NSF are by far the most active federal agencies in responding to allegations and making findings of research misconduct.²⁰ ORI has made over 160 confirmed findings of misconduct since 1992 and averages approximately thirteen findings a year.²¹

14. *Id.* § 93.319; see Office of Research Integrity, Handling Misconduct—Inquiry Issues, http://ori.dhhs.gov/misconduct/inquiry_issues.shtml (last visited Feb. 22, 2007).

15. *See id.*

16. *See id.*

17. *Id.*

18. Federal Policy on Research Misconduct, 65 Fed. Reg. 76,260, 76,260-64 (Dec. 6, 2000).

19. See Office of Research Integrity, Policies—Federal Policies, http://ori.dhhs.gov/policies/federal_policies.shtml (last visited Feb. 22, 2007).

20. See COUNCIL ON GOVERNMENTAL RELATIONS, ACCESS TO AND RETENTION OF RESEARCH DATA: RIGHTS AND RESPONSIBILITIES 19 (2006), available at <http://206.151.87.67/docs/CompleteDataRetentionBooklet.doc>.

21. LAWRENCE J. RHOADES, ORI CLOSED INVESTIGATIONS INTO MISCONDUCT ALLEGATIONS INVOLVING RESEARCH SUPPORTED BY THE PUBLIC HEALTH SERVICE: 1994-2003, at 6 (2004); Chris

III. ADDITIONAL AUTHORITIES DELEGATED TO ORI

ORI has been delegated additional authority to promote research integrity and prevent research misconduct through education and training in the responsible conduct of research, activities designed to promote research integrity and prevent research misconduct, and research and evaluation programs.²² Under this additional authority, ORI has been very active in sponsoring workshops and conferences related to research misconduct, research integrity, and education in the responsible conduct of research.²³

A. *Maintaining the Responsible Conduct of Research Program*

Since the year 2000, ORI has invested hundreds of thousands of dollars in promoting responsible research practices in the research community.²⁴ A workshop and conference program provided a platform for individual research institutions and scientific associations to discuss scientific topics such as research misconduct, authorship responsibilities, mentoring, protection of human subjects, clinical research, standards of conduct within specific scientific disciplines, new emerging issues, such as the importance of financial conflicts of interest, and other topics important to the scientific community and individual scientific disciplines.²⁵

ORI also developed the Responsible Conduct of Research (“RCR”) program, a resource development program that provides funding to research institutions and others to produce educational programs and tools that could be used to educate scientists and institutions on a variety of topics. The RCR resource program has made fifty awards, with thirty projects completed and posted on the ORI website for use by national and international scientists and research institutions.²⁶ ORI has also

B. Pascal, Director of ORI, The Role of HHS Office of Research Integrity in Investigating Research Misconduct, Statement Before the Subcommittee on Criminal Justice, Drug Policy and Human Resources Committee on Government Reform (Mar. 7, 2006).

22. Statement of Organization, Functions, and Delegations of Authority, 65 Fed. Reg. 30,600, 30,600-01 (May 12, 2000).

23. See, e.g., Office of Research Integrity, Conferences—Past Conferences, http://ori.dhhs.gov/conferences/past_conf.shtml (last visited Feb. 22, 2007).

24. See, e.g., ORI, ANNUAL REPORT 2005, at 19, available at http://ori.dhhs.gov/documents/annual_reports/ori_annual_report_2005.pdf (observing that the ORI awarded a total of \$225,000 for the creation of “Internet-based assessment and instructional materials on peer review, data management, mentoring, and laboratory management” in 2005).

25. See generally NICHOLAS H. STENECK, ASSESSING THE INTEGRITY OF PUBLICLY FUNDED RESEARCH: A BACKGROUND REPORT FOR THE NOVEMBER 2000 ORI RESEARCH CONFERENCE ON RESEARCH INTEGRITY (2000).

26. See Office of Research Integrity, RCR—Research Development Program,

funded discrete products in house, such as the “ORI Introduction to the Responsible Conduct of Research,” which has sold thousands of copies and been translated into Chinese, Japanese and Korean.²⁷ This booklet covers the nine key elements of responsible research, including research misconduct, the protection of human subjects, the welfare of laboratory animals, conflicts of interest, data management practices, mentoring and trainee responsibilities, collaborative research, authorship and publication, and peer review.²⁸

ORI also funded, in collaboration with the American Association of Medical Colleges (“AAMC”), research integrity activities by scientific societies and associations. This project lasted for four years and funded thirty-nine awards to thirty-three academic societies.²⁹ Many societies held conferences and workshops and developed specific products on topics such as conflict of interest and education in the responsible conduct of research.

ORI has also contracted with the University of Miami, Collaborative Institutional Training Initiative (“CITI”) program to develop a web-based RCR education program that would be available worldwide for researchers, administrators, students, post-docs and others.³⁰ This program will be provided to users free of charge and, once operational, should increase RCR education training to thousands of additional scientists, research administrators and other interested parties.³¹

B. Assuring the Integrity of the Scientific Literature

ORI believes it is important to the research community, individual scientists, and the public to correct or retract scientific articles that are falsified, fabricated, or simply incorrect. Between 1992 and 2006, ORI corrected or retracted 138 articles.³² ORI cannot do this acting alone, but

<http://ori.dhhs.gov/education/rcrrdp/> (last visited Feb. 22, 2007).

27. See Office of Research Integrity, International—Activity, <http://ori.dhhs.gov/international/activity/KoreansGetORIText.shtml> (last visited Feb 22, 2007); *ORI Intro to RCR Available for Fall*, ORI NEWSL. (ORI/U.S. Dep’t of Health & Human Servs., Rockville, Md.), Mar. 2006, at 3, available at <http://ori.hhs.gov/publications/documents/Mar06ORINewsletter.pdf>.

28. See NICHOLAS H. STENECK, ORI INTRODUCTION TO THE RESPONSIBLE CONDUCT OF RESEARCH, at vii-ix (2004).

29. See Office of Research Integrity, AAMC Funded Projects for RCR, http://ori.hhs.gov/education/aamc_funded_1-3.shtml (last visited Feb. 22, 2007).

30. See Paul Braunschweiger, *CITI RCR Course Offers Customized Instruction*, ORI NEWSL. (ORI/U.S. Dep’t of Health & Human Servs., Rockville, Md.), Dec. 2006, at 1, available at <http://ori.dhhs.gov/publications/documents/Dec06-ORI-Newsletter.pdf>.

31. See *id.*

32. ORI, U.S. DEP’T OF HEALTH & HUMAN SERVS., MANAGING ALLEGATIONS OF SCIENTIFIC MISCONDUCT: A GUIDANCE DOCUMENT FOR EDITORS 4 (2000) [hereinafter GUIDANCE

relies on the appropriate journals to cooperate in correcting the literature.³³ Most journals have been very helpful in that regard. Sometimes journals become aware of false or incorrect articles and retract or correct them on their own accord, before ORI has completed its actions in a specific case.

In addition, many institutions will correct or retract articles when they become aware of a problem with a published article. The need to take action may become evident when an allegation of misconduct is made at the institution or the PI reviews a manuscript or published article and realizes that the data does not support the findings and conclusions in the paper.

ORI will take action to correct the literature in response to a finding of research misconduct when it concludes that an article is falsified or fabricated.³⁴ ORI will take steps to impose an administrative action, which requires the scientist to make corrections or retractions to the article consistent with the findings of misconduct.³⁵ This is often implemented through a voluntary exclusion agreement that requires the scientist to submit a letter to the appropriate journal asking for the retraction or correction, consistent with the terms of the written agreement.³⁶ In two recent ORI cases, which have been made public and are posted on the ORI website, many articles were retracted and corrected as part of the administrative actions taken against the accused scientist.

In the case of Eric Poehlman, a scientist previously employed by the University of Vermont (“UVM”), ORI required and Dr. Poehlman agreed, to ten retractions and corrections of the literature as part of the settlement of ORI’s misconduct findings against the investigator.³⁷ This case also included criminal and civil actions against Dr. Poehlman based on actions taken by the United States Attorney’s Office in Vermont and by the HHS Office of Inspector General. ORI staff participated in reviewing the UVM investigation report and made twenty additional research misconduct findings based on ORI analysis of the research data.³⁸ The Poehlman case is a good example of how ORI participates in

DOCUMENT].

33. *See id.* at 9.

34. *See* 42 C.F.R. § 93.103.

35. *Id.* § 93.407(a)(1).

36. *See, e.g.*, Notice on Findings of Scientific Misconduct, 70 Fed. Reg. 15,092, 15,095 (Mar. 24, 2005).

37. Press Release, Office of Research Integrity, Dr. Eric T. Poehlman (Mar. 17, 2005), available at http://ori.dhhs.gov/misconduct/cases/press_release_poehlman.shtml.

38. *See* Susan R. Morrissey, *Research Misconduct*, CHEMICAL & ENGINEERING NEWS, Nov. 6, 2006, at 18, 22, available at <http://pubs.acs.org/cen/government/84/8445gov1.html>.

civil and criminal investigations conducted by the United States Attorney's Office and the HHS Office of Inspector General. Dr. Poehlman was sentenced to jail time for one year and one day and paid the federal government \$180,000 as a civil fraud fine due to the extensive fraud.³⁹

In another recent case involving Dr. Leadon from the University of North Carolina, Chapel Hill, several articles were retracted and corrected based on an ORI settlement agreement with Dr. Leadon. Additional articles were separately retracted based on decisions made by the relevant scientific journals.⁴⁰

*C. Journal Policies that Can Facilitate Responding
to Possible Research Misconduct*

In 2000, ORI published *Managing Allegations of Scientific Misconduct: A Guidance Document* ("Guidance Document").⁴¹ It states:

[Journal] editors have a responsibility to pursue possible scientific misconduct in manuscripts submitted to or published in their journals and to publish a retraction of any fraudulent paper published in their journals. However, editors are not responsible for conducting a full investigation or deciding whether scientific misconduct occurred. Those responsibilities rest with the institution where the work was conducted or with the funding agency.⁴²

In order to assist journal editors in meeting this responsibility, ORI suggests that journals adopt clear, specific policies that inform all authors who submit a manuscript that as a *condition of submission*, the authors must agree to permit the journal to refer any manuscript that the journal, in its sole discretion, determines is a suspicious manuscript and warrants submitting the manuscript to the submitting institution or funding agency for review, investigation, or other appropriate action.⁴³ Journal policy should also state that the journal is relieved of any liability due to wrongful action taken by the institution or funding agency.⁴⁴

The Guidance Document further states:

39. See Press Release, Office of Research Integrity, Dr. Eric T. Poehlman (Mar. 17, 2005), available at http://ori.dhhs.gov/misconduct/cases/press_release_poehlman.shtml.

40. See Notice on Findings of Scientific Misconduct, 71 Fed. Reg. 33,308, 33,308-09 (June 8, 2006).

41. See GUIDANCE DOCUMENT, *supra* note 32.

42. *Id.* at 3.

43. See *id.* at 10.

44. See *id.*

The Council of Biology Editors [now named the “Council of Science Editors”], a professional association of editors of many of the world’s leading biomedical journals, has examined this issue and its Editorial Policy Board recently drafted language for the purpose of aiding journals with this task. The policy statement reads:

Should possible scientific misconduct or dishonesty in research submitted for review by the journal be suspected or alleged, the journal reserves the right to forward any submitted manuscript to the sponsoring or funding institution or other appropriate authority for investigation. The journal recognizes the responsibility to ensure that the question is appropriately pursued, but does not undertake the actual investigation or make determinations of misconduct.⁴⁵

D. Publishing ORI Research Misconduct Cases

Although ORI believes strongly that confidentiality must be respected when an individual is accused of research misconduct, it also believes that misconduct must be publicly reported when it is confirmed.⁴⁶ Public reporting of research misconduct informs the public of real or potential harm when the misconduct is serious and may affect clinical research or clinical trials. Furthermore, it prevents scientists from going underground and ending up at a new institution where the scientist can once again have an opportunity to commit misconduct.

When journal articles are fraudulent, public exposure provides the opportunity to correct the scientific literature and to notify other scientists working in the same field that there are fraudulent articles upon which they cannot rely. Finally, publicity has a potential deterrent effect. As other researchers learn about real cases of research misconduct that may end a scientist’s career, those who might be tempted may think twice about the risks of committing research misconduct.

Publicity can also have an educational component. By hearing about real cases of misconduct, other scientists will realize that misconduct is possible and may be more attentive to some of the weaknesses in scientific research. This could broaden their understanding of the way in which research is actually conducted and encourage some investigators to focus on doing only high quality and

45. *Id.* (quoting Personal Communication from Council of Biology Editors, Chair of Editorial Policy Board to ORI (July 1998)).

46. *See* 42 C.F.R. § 93.108.

ethical research even when it appears to slow down scientific progress. Engaging in high quality research all the time may, in fact, be the most efficient and cost effective way to conduct research and produce important new discoveries.

E. ORI Assurance Program

Consistent with the PHS regulation, ORI requires all PHS-funded institutions to report annually the number of allegations received and inquiries and investigations conducted on research misconduct.⁴⁷ Institutions must file an annual report to maintain their assurance, a requirement for them to apply for and receive PHS research funds.⁴⁸ The institutions must also certify that they have an institutional policy on research misconduct that is consistent with the regulation.⁴⁹ In order to facilitate quality institutional policies, ORI has developed a model policy for research misconduct that is consistent with the PHS regulation. This model policy was posted on the ORI website in November 2006 for comment by research institutions.⁵⁰ The comment period was sixty days.⁵¹ Following the comment period, ORI is considering some additional edits to the model policy before posting the policy on the ORI website.⁵²

Institutions, however, are not required to adopt the model policy.⁵³ They may pick and choose those parts of the model policy that they find helpful and ignore the rest, so long as the institutional policy is consistent with the regulation.⁵⁴ ORI has suggested several optional policies that may prove beneficial to the institution.

Below are a few examples of these optional policies that institutions may find helpful.

47. *See id.* § 93.302(b).

48. *Id.* § 93.301.

49. *Id.* § 93.304.

50. Office of Research Integrity, Policies: ORI Model Policy for Responding to Allegations of Scientific Misconduct, http://web.archive.org/web/20060519180130/http://ori.dhhs.gov/documents/model_policy_responding_allegations.pdf (last visited Feb. 22, 2007).

51. *See ORI Asks for Comments on Research Misconduct Policy*, BIORESEARCH COMPLIANCE REP., Nov. 8, 2006, <http://www.fdainfo.com/bicoonlinepages/BiCoOnline110806.htm> (online update page) [hereinafter *ORI Asks for Comments*].

52. Office of Research Integrity, Policies: ORI Model Policy for Responding to Allegations of Scientific Misconduct, <http://ori.dhhs.gov/policies/documents/ModelPolicyrblfinal10GCCCMCommentsrblrevdraftfinal102006.pdf> (last visited Feb. 22, 2007).

53. *ORI Asks for Comments*, *supra* note 51.

54. *Id.*

1. Adopt Additional Standards

Under 42 C.F.R. § 93.319, institutions may adopt additional standards of conduct that go beyond the PHS standards in Part 93. These standards may be included in the same policy document as the PHS standards. The additional standards will apply only to the internal activities of the institution.

The University of Maryland, Baltimore, has adopted the following additional policies at the institution, regarding misconduct in scholarly work.⁵⁵

1. It should be emphasized that reporting misconduct in scholarly work is a responsibility shared by everyone at the institution. However, frivolous, mischievous or malicious misrepresentation in alleging misconduct will not be tolerated.
2. Misconduct in scholarly work may take many forms; these guidelines apply, but are not limited to, the following examples of misconduct:
 1. Falsification of data. Ranging from fabrication to deceptively selective reporting, including the purposeful omission of conflicting data with the intent to falsify results.
 2. Improper experimental manipulation. For example, manipulating experiments to obtain biased data.
 3. Plagiarism. For example, taking credit for an exact copy or the rewritten or rearranged work of another.
 4. Improper assignment of credit. For example, insufficiently or knowingly not citing the work of others, including associates and students, or inadequately identifying the repetition of data or material that appears in more than one publication.
 5. Abuse of confidentiality. For example, improper use of information gained by privileged access, such as information obtained through service on peer review panels and editorial boards.
 6. Deliberate violation of regulations. For example, failure to comply with regulations concerning the use of human subjects, the care of animals, or health and safety of individuals and the environment.
 7. Misappropriation of funds or resources. For example, the misuse of funds for personal gain. . . .
3. Allegations of misconduct in scholarly work may come from various sources within and without the institution. It is important

55. Univ. of Md., Balt., USM/UMB Policies and Procedures, <http://cf.umaryland.edu/hrpolicies/section3/t30110sa.html> (last visited Feb. 22, 2007).

that allegations of misconduct be handled expeditiously and that no serious allegations go unheeded. Consequently, each campus must develop specific procedures that define how allegations will be evaluated, what levels of administration will be involved, and what actions will be taken as the result of evaluating an allegation of misconduct.

4. No decisions regarding the seriousness of an allegation of misconduct should be made by anyone whose personal or professional interests may be involved. Thus, although an allegation may first be reported to a collaborator, a co-worker, a co-author, a faculty advisor, or a team leader, such a close associate must report the allegation to a designated senior official for further action.
5. The purpose of the evaluation of an allegation is to determine whether there is or is not substantial basis to believe that scholarly misconduct has occurred, and whether formal discharge proceedings or other action with respect to the individual's employment is warranted.⁵⁶

2. Maintain Two Research Integrity Officers

The regulation requires a "research integrity officer" ("RIO") to manage allegations of research misconduct.⁵⁷ Some institutions have more than one campus, such as a medical school and a graduate school. Thus, the institution may find it to be more effective to have two RIOs, one for each campus.

3. Allow Complainant to Comment on Investigation

Under the new regulation, the complainant no longer has the right to review and comment on the inquiry and investigation.⁵⁸ However, since the complainant is often the most knowledgeable person about the alleged misconduct, the institution may find it helpful to get comments from the complainant on the inquiry and investigation reports. Thus, as an option, the institution may permit the complainant to review and comment on the inquiry and investigation reports, subject to a written agreement that the complainant will maintain the confidentiality of the information obtained. This is required because the regulation protects the confidentiality of the accused individual.

56. *Id.* (cross-references omitted).

57. *See* 42 C.F.R. § 93.301(b).

58. *See id.* § 93.308(b); Office of Research Integrity, Policies—Regulations: Questions and Answers—42 C.F.R. pt. 93, <http://ori.hhs.gov/policies/QA-Reg-6-05.shtml> (last visited Feb. 22, 2007).

IV. THE IMPORTANCE OF THE RESEARCH DATA: TOP TEN THINGS FOR THE LAB CHIEF OR PI TO AVOID IN THE LABORATORY

ORI believes that the research data is the most important output of the research process. However, for the data to be useful, it must be accurate, based on the actual research records, and interpreted and reported honestly. The tendency of some scientists to stretch the truth to get published or funded undermines the trustworthiness of the science and harms public confidence in the products and treatments that result from the research enterprise. ORI encourages all players in the research enterprise to promote the transparency and accuracy of the research findings to the greatest extent possible.

The following is a list of the top ten things for the lab chief or PI to avoid in the laboratory in order to maintain the integrity of research data:

1. Fail to review the raw data prior to publication; accept summary data or prepared tables or graphs instead.
2. On a project where expected results have not been achieved over several months, demand significant results immediately to meet a publication or grant deadline, which can dramatically increase pressure on the staff to manipulate the data to support the desired outcome.
3. Hire a new post-doc who comes highly recommended, but leave him or her without guidance or supervision.
4. Tell your staff to do the right thing, but do the convenient thing when it is expedient.
5. Publish the results of a team research project, but leave out one or two members of the team who made substantive contributions and met the criteria for authorship.
6. Provide no specific guidance or standards for keeping laboratory data. Let each lab member choose his or her own technique for handling data.
7. Tell your lab members to ask questions, but don't make yourself available because you are too busy.
8. Have a large lab of junior scientists and provide little supervision or guidance.
9. Drop data points in order to "clean up" your graph or table without a clear scientific rationale that an outsider who understands the experiment would consider legitimate.
10. Tell the lab tech what results you expect from the experiment and that you need the results right away.

Many junior scientists will do their best to give the Lab Chief or PI what he or she expects, even if the scientist has to make the data "fit" the request. This is especially true, when the junior staff is in an insecure

position, such as a temporary position, receiving soft money, or on a green card. A recent study indicates that many scientists deviate from scientific norms of behavior, especially at major stress points, such as submitting an article for publication or seeking grant support.⁵⁹ To ensure that the research is correctly reported, the PI should review the raw data carefully before publication and grant submission, involve the junior staff as appropriate in discussing and interpreting the data, and set expectations for lab staff on collecting and maintaining the data, so that it is available to the PI and staff.

A recent ORI study found that about twenty-five percent of PIs did not spend adequate time supervising staff, reviewing the data, and otherwise managing the laboratory and training junior staff.⁶⁰ This creates risks in the lab that the research may be sloppy, not reported properly, and may encourage staff to commit research misconduct and engage in questionable research practices that do not meet the norms of good scientific behavior.

V. A FEW LEGAL ISSUES RELEVANT TO INTEGRITY

A. Confidentiality

ORI has a long history of providing confidentiality for individuals who are accused of research misconduct. When ORI was officially established in 1993, it became very clear to ORI and the research community that confidentiality was a core requirement for accused scientists to protect their reputations, until a determination of research conduct was made, and beyond the proceedings if it was concluded that actionable research did not occur. If the name of the accused individual was released before a finding was made, there would always be a cloud over the accused, even if he or she were subsequently exonerated.⁶¹ This principle of confidentiality has existed to this day and I believe the science community regards it as a fundamental requirement for fairness in the system for responding to allegations of misconduct.

59. See Brian C. Martinson et al., *Scientists Behaving Badly*, 435 NATURE 737, 737-38 & tbl.1 (2005).

60. See AM. INSTS. FOR RESEARCH, SURVEY OF RESEARCH INTEGRITY MEASURES UTILIZED IN BIOMEDICAL RESEARCH LABORATORIES: FINAL REPORT 88, 41 exhibit 12 (2003), available at http://ori.dhhs.gov/documents/research/integrity_measures_final_report_11_07_03.pdf; Jim Giles, *Breeding Cheats*, 445 NATURE 242, 243 (2007), available at <http://www.nature.com/nature/journal/v445/n7125/full/445242a.html#B5> (interpreting data from the report to conclude that "one in four lab heads did not take their supervisory roles seriously enough").

61. See RESEARCH TRIANGLE INST., SURVEY OF ACCUSED BUT EXONERATED INDIVIDUALS IN RESEARCH MISCONDUCT CASES: FINAL REPORT 86-87 (1996).

This confidentiality requirement is codified in § 93.108 of the PHS regulation, and mentioned numerous times in that regulation. Additionally, only a small percentage of misconduct allegations made against accused scientists result in misconduct findings. Thus, confidentiality protection is critical to the process because it protects the reputations of those scientists who have not committed misconduct. Further, the federal Privacy Act⁶² also applies to ORI research misconduct records.⁶³

Consistent with these principles, ORI neither admits nor denies any specific matter when it receives a request for information regarding any misconduct case, or suspected case of misconduct.⁶⁴ In accordance with HHS policy on federal document requests, ORI forwards such requests to the Public Health Service Freedom of Information Act (“FOIA”) Office for processing as a FOIA request.⁶⁵ In balancing these policy considerations, courts agree. In *McCutchen v. HHS*, the United States Court of Appeals for the District of Columbia ruled, in a decision under the FOIA, that the privacy of accused scientists who had not been found guilty of research misconduct outweighed the public interest in the disclosure of the names of the accused.⁶⁶

B. Institutional Liability

After he was accused of scientific misconduct, Dr. Kimon Angelides filed a civil suit in Texas state court against the Baylor College of Medicine, and several of its employees who served on the inquiry and investigation committees, for slander and other torts.⁶⁷ A trial date was set, but before the trial was completed, the case was settled and dismissed after the HHS Departmental Appeals Board upheld the ORI findings of misconduct against Dr. Angelides.⁶⁸

C. Protections for Complainants Who Make Good Faith Allegations of Research Misconduct

The PHS regulation states that the institution must “[t]ake all reasonable and practical steps to protect the positions and reputations of

62. 5 U.S.C. § 552a (2000).

63. 42 C.F.R. § 93.414.

64. *See id.* § 93.108.

65. *See, e.g.*, Office of Research Integrity, ORI Handbook, http://ori.hhs.gov/documents/rio_handbook.pdf (last visited Feb. 22, 2007).

66. 30 F.3d 183, 188-89 (D.C. Cir. 1994).

67. *See Angelides v. Baylor Coll. of Med.*, 117 F.3d 833, 835 (5th Cir. 1997).

68. *See Kimon J. Angelides*, Dep’t of Health & Human Servs. Appeals Bd., Decision No. 1677, at 1 (Feb. 5, 1999).

good faith complainants, witnesses and committee members and protect them from retaliation by respondents and other institutional members.”⁶⁹ To act in good faith, the complainant must have “a belief in the truth of one’s allegation . . . that a reasonable person in the complainant’s . . . position could have based on the information known to the complainant . . . at the time.”⁷⁰ However, “[a]n allegation or cooperation with a research misconduct proceeding is not in good faith if made with knowing or reckless disregard for information that would negate the allegation or testimony.”⁷¹

D. Defamation and Breach of Confidentiality

Even if an allegation is made in good faith, it is important not to make public disclosures about the allegation. If an allegation is not proven and it is made public by the complainant, there is the possibility that the complainant can be sued for defamation or invasion of privacy. If there are concerns about how to report misconduct, the complainant should be careful to seek advice from the institutional RIO or from ORI before making an allegation.

In one such case, Dr. Gerald Rosen, a scientist at the University of Maryland Baltimore, was accused of scientific misconduct by Dr. Carmen Arroyo.⁷² Dr. Rosen sued Dr. Arroyo for defamation and invasion of privacy and was awarded a jury verdict of about \$75,000 which was upheld on appeal. The Maryland Court of Special Appeals ruled that Dr. Arroyo did not have an absolute privilege to report her allegations of misconduct. There was also evidence that Dr. Arroyo repeated her allegations after the University of Maryland and the Veteran’s Administration concluded that Dr. Rosen had not committed research misconduct.⁷³ In addition, the court found evidence that Dr. Arroyo further disclosed the allegation to the *Baltimore Sun*, which constituted an invasion of privacy.⁷⁴

E. Intentional Interference with a Scientist’s Research Project

In the case of *United States v. Arora*, a Maryland court ruled that Dr. Prince Kumar Arora “undermined the honor system that exists among the community of scientists, a system which is ultimately based

69. 42 C.F.R. § 93.300(d).

70. *Id.* § 93.210.

71. *Id.*

72. *Arroyo v. Rosen*, 648 A.2d 1074, 1075 (Md. Ct. Spec. App. 1994).

73. *See id.* at 1076, 1078.

74. *Id.* at 1080.

on ‘truthfulness, both as a moral imperative and as a fundamental operational principle in the scientific research process.’”⁷⁵ Dr. Arora intentionally destroyed the cells of another scientist while conducting a government research project. The court required Dr. Arora to pay \$450.20 in compensatory damages and \$5000 in punitive damages.⁷⁶ This case demonstrates that even when formal research misconduct is not found, a scientist who violates scientific norms can still be held accountable on other grounds.

F. Institutional Authority to Take Action When ORI Declines

In *Shovlin v. University of Medicine and Dentistry of New Jersey*, the court stated: “Even though the federal agency [ORI] to which the university reported may not have considered duplicate publication to constitute ‘misconduct in science,’ it recognized the University’s right to hold such a practice to be unacceptable.”⁷⁷ In this case, the individual had published the same paper twice, which violates most journal policies. Journals, typically in the instructions to authors, specify that the work must be original and not previously published.⁷⁸ While ORI did not consider duplicate publication (sometimes called self-plagiarism) to be research misconduct under ORI’s jurisdiction, it acknowledged that an institution could do so under its own policies. The court concurred.⁷⁹

G. ORI Policy on Plagiarism

Although there is widespread agreement in the scientific community on including plagiarism as a major element of the PHS definition of scientific misconduct, there is some uncertainty about how the definition of plagiarism itself is applied in ORI cases.

As a general working definition, ORI considers plagiarism to include both the theft or misappropriation of intellectual property and the substantial unattributed textual copying of another’s work. It does

75. 860 F. Supp. 1091, 1101 (D. Md. 1994) (quoting PANEL OF SCIENTIFIC RESPONSIBILITY & THE CONDUCT OF RESEARCH, COMM. ON SCI., ENG’G, & PUB. POLICY, NAT’L ACAD. OF SCI., ENSURING THE INTEGRITY OF THE RESEARCH PROCESS 17 (1992)).

76. *Id.*

77. 50 F. Supp. 2d 297, 314 (D.N.J. 1988).

78. *See, e.g.*, International Committee of Medical Journal Editors, Uniform Requirements for Manuscripts Submitted to Biomedical Journals, <http://www.icmje.org> (last visited Feb. 22, 2007) (stating that upon finding of a redundant or duplicate manuscript, “prompt rejection of the submitted manuscript should be expected” by the author); Journal of Abnormal Psychology, Instructions to Authors, <http://www.apa.org/journals/abn/submission.html> (last visited Feb. 22, 2007) (proscribing the “publication of any manuscript that has already been published in whole or substantial part elsewhere”).

79. *See Shovlin*, 50 F. Supp. 2d at 318.

not include authorship or credit disputes.

The theft or misappropriation of intellectual property includes the unauthorized use of ideas or unique methods obtained by a privileged communication, such as a grant or manuscript review.

Substantial unattributed textual copying of another's work means the unattributed verbatim or nearly verbatim copying of sentences and paragraphs which materially mislead the ordinary reader regarding the contributions of the author. ORI generally does not pursue the limited use of identical or nearly-identical phrases which describe a commonly-used methodology or previous research because ORI does not consider such use as substantially misleading to the reader or of great significance.

Many allegations of plagiarism involve disputes among former collaborators who participated jointly in the development or conduct of a research project, but who subsequently went their separate ways and made independent use of the jointly developed concepts, methods, descriptive language, or other product of the joint effort. The ownership of the intellectual property in many such situations is seldom clear, and the collaborative history among the scientists often supports a presumption of implied consent to use the products of the collaboration by any of the former collaborators.

For this reason, ORI considers many such disputes to be authorship or credit disputes rather than plagiarism. Such disputes are referred to PHS agencies and extramural institutions for resolution.⁸⁰

VI. CONCLUSION

ORI's primary responsibilities in research misconduct and research integrity include establishing regulations to provide a framework for action by research institutions that receive PHS funds, providing leadership in promoting positive actions in research institutions and the scientific community to promote the responsible conduct of research, encouraging good data practices, and other activities to improve the research enterprise.

This cannot be accomplished without the support, collaboration, and tireless efforts of many scientific societies and associations, research institutions, and individual scientists and members of the public. We should acknowledge with great gratitude their inspiration, good will, and wise advice over many years.

80. *ORI Provides Working Definition of Plagiarism*, ORI NEWSL. (ORI/U.S. Dep't of Health & Human Servs., Rockville, Md.), Dec. 1994, at 5-6.