I. Introduction

Compliance in all areas of research has never been more in question, or more important. Any misstep may end up in the press, the subject of a complaint by a human subject, or the focus of a governmental enforcement action. More importantly, noncompliance, such as research misconduct, erodes the public’s trust in scientific advancement and creates a faulty foundation upon which future science may be based. In essence, federal research dollars are diverted to studies that do no warrant funding, and leave a more limited pool of resources for otherwise valid research, which could benefit society as a whole. Although we must all recognize that there are pressures in the research community, i.e., “publish or perish”, stellar ongoing research results to support continued funding, prestige and tenure, no pressures are worth the price to be paid for such misconduct.

The topic of research compliance is sufficiently large to fill a tome. In this paper, we address the specific area of research misconduct. We discuss the most recent regulations promulgated by the Department of Health and Human Services’ (“HHS”) Office of Research Integrity (“ORI”), effective June 16, 2005, that (1) define research misconduct; (2) outline an institution’s obligations to investigate and respond to allegations of research misconduct; and (3) set forth the ORI’s authority to respond to reports of misconduct.\(^1\) We have chosen to concentrate on this policy because it was recently revised, is more specific and detailed than the policies of NSF or the other federal agencies, and is more relevant for biomedical research. We also highlight recent, prominent research misconduct cases to demonstrate the significant toll such misconduct may take on researchers and their institutions.

II. Research Misconduct - In General

Research misconduct may be as egregious as falsifying case report forms to reflect data from human subjects who do not exist, stealing another researcher’s ideas or results without appropriately giving attribution to such ideas, or manipulating research data to show support for the research hypothesis when, in fact, the true results do not. Such egregious conduct is actionable as “research misconduct” as it meets the regulatory definition of 42 C.F.R. § 93.103. It is this level of misconduct that we will address given that it is this level of activity that is subjected to enforcement actions by the ORI, the Department of Justice (“DOJ”) and the Office of the Inspector General (“OIG”) of the Department of Health and Human Services (“HHS”).

However, before exploring this level of activity, it is interesting to highlight two important studies that have examined research misconduct among federally-sponsored researchers in recent

\(^{1}\) 70 Fed. Reg. 28,370 (May 17, 2005).
years. First, a study published in the June 2005 edition of Nature, found that approximately 33 percent of American biomedical scientists reported engaging in some level of research misconduct during the previous three years. The researchers surveyed 3,600 mid-career scientists and 4,160 early career scientists, all of whom received some funding from the National Institutes of Health ("NIH"). The survey results indicated that respondents admitted to: (1) falsifying research data (0.3%); (2) using another’s ideas without obtaining permission or giving credit (1.4%); (3) unauthorized use of confidential information (1.7%); (4) failing to present data that contradicted the researcher’s own previous research (6.0%); (5) shortcutting minor aspects of human-subjects protection requirements (7.6%); and (6) changing the design, methodology or results of a study in response to pressure from a funding source (15.5%). Although only some of the above activities are covered by the regulations at issue, the breadth and pervasiveness of other “lesser” misconduct highlights the need for strong institutional dedication to research compliance, as even this level of misconduct negatively impacts research.

In a similar 2005 survey commissioned by ORI, The Gallup Organization found that of 2,212 researchers receiving NIH grants, 201 reported instances of likely federally-defined misconduct over a three (3)-year period, of which 60 percent involved the fabrication or falsification of research data and 36 percent involved plagiarism. Gallup further suggests in a subsequent edition of their report, that if taken into consideration the entire population of scientists supported by NIH in 2007 (about 155,000), under the most conservative assumptions, a minimum of 2,325 possible acts of research misconduct occur each year. The authors of this report confirmed that “there is awareness by scientists that there is a degree of misbehaviors by scientists.” Considering the present data, however, they caution that “for every three observations of possible misconduct there was also one observation of misbehavior that was viewed by scientists as on a par with misconduct.” Certainly, as the authors conclude, “[the ORI report] will contribute to the ongoing dialogue on research misconduct as well as what role departments, institutions and the federal government should take to promote greater research integrity.”

III. Who Oversees Research Misconduct?

A. The ORI

ORI is charged with the responsibility of overseeing and pursuing matters of scientific misconduct. Specifically, the ORI oversees and directs Public Health Service (“PHS”) research integrity activities on behalf of the Secretary. However, regulatory research integrity activities of the Food and Drug Administration (“FDA”), are reviewed and pursued by the FDA, and those relevant to other federal agencies (non-PHS) are handled by those agencies.

The ORI is located within the Office of Public Health and Science in the Office of the Secretary of HHS. ORI’s responsibilities are to:

- Develop policies, procedures and regulations related to the detection, investigation, and prevention of research misconduct and the responsible conduct of research;

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• Review and monitor research misconduct investigations conducted at applicant and awardee institutions, intramural research programs, and the OIG;
• Recommend research misconduct findings and administrative actions;
• Implement activities and programs to teach responsible conduct of research, promote research integrity, prevent research misconduct;
• Provide technical assistance to institutions that respond to allegations of research misconduct;
• Conduct policy analyses, evaluations and research to build the knowledgebase in research misconduct, research integrity, and prevention and to improve HHS research integrity policies and procedures;
• Assist the Office of General Counsel to present cases before HHS Departmental Appeals Board;
• Administer programs for: maintaining institutional assurances, respond to allegations of retaliation against whistleblowers, approve intramural and extramural policies and procedures, and respond to Freedom of Information Act and Privacy Act requests.4

B. The ORI Assurance Program

The ORI Assurance and Compliance Program is designed to monitor institutional compliance with PHS Policies on Research Misconduct. An institution’s receipt of PHS funding is conditioned upon its filing an assurance (“Assurance”) with ORI stating that it: (1) has developed policies and procedures in compliance with these Regulations for inquiring into and investigating allegations of research misconduct; and (2) complies with its own policies and procedures and these regulatory requirements.5

An institution may establish an Assurance when an official signs the face-page of the PHS-398 application form or when it files a separate assurance form with ORI. An “Assurance” is a written certification statement signed by the research site’s “Institutional Official” as to the institution’s compliance. The institution must file an annual report with ORI which contains certifications as to ongoing compliance. Institutions must also submit their policy for responding to allegations of research misconduct for review when requested by ORI, revise their policy when requested by ORI to bring the policy into compliance with the PHS regulation, and comply with the PHS regulation. Lack of an appropriate assurance can result in fines and penalties imposed by ORI.

IV. Overview of the “New” Regulation

On May 17, 2005, ORI published the Policies on Research Misconduct final rule (“Final Rule” or “Regulations”) that replaced less comprehensive regulations that had governed scientific misconduct since 1989.6 The new regulations became effective on June 16, 2005.

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4 http://ori.dhhs.gov.
5 42 C.F.R. § 93.301.
6 42 C.F.R. Part 93, replacing 42 C.F.R. Part 50, subpart A.
Although the Final Rule only applies to research funded, at least in part, by PHS, it now applies to PHS support beyond grants and cooperative agreements, and includes support provided through contracts and through direct funding of PHS intramural research programs. This increase in scope expands the type of research that could be subject to allegations of scientific misconduct and the types of research governed by ORI. Additionally, the regulations apply regardless of whether an application or proposal for PHS funds ultimately results in a grant, contract or other form of PHS support.

The Final Rule also extends the rules related to plagiarism to include plagiarism during the journal peer review process. In other words, the Final Rule applies to research written work that is being reviewed through peer review prior to final publication when that work was supported in whole or in part by PHS. Finally, the statute of limitations for raising an allegation of scientific misconduct is six (6) years from the date that the alleged misconduct actually occurred.

The Final Rule describes the responsibilities of research institutions, as well as HHS, PHS and ORI, in responding to allegations of “research misconduct,” which is defined to include “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.” (See Section V.B. below).

Significantly, the Regulations require institutions to implement and/or strengthen internal policies and procedures for reporting and responding to allegations of research misconduct. For instance, institutions must have satisfactory written policies on (among other things):

- responding “thoroughly, competently, objectively, and fairly” to allegations of research misconduct;
- ensuring that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional, or financial conflicts of interest with the complainant, respondent, or witnesses;
- notifying ORI of any decision to open an investigation on or before the date on which the investigation begins;
- allowing the subject of a research misconduct proceeding (the “Respondent”) to provide written comments on the institution’s draft report of the investigation (and establishing procedures for the institutional investigation committee to consider and address the Respondent’s comments before issuing the final report);
- handling the research record and evidence;
- protecting and restoring (as appropriate) the reputation of persons alleged to have engaged in research misconduct or any person reporting misconduct (the “Complainant”), witness, or investigation committee member; and
- protecting the confidentiality of Respondents, Complainants, and research subjects who may be identified in research records or evidence.

In finalizing the regulations, HHS:
- confirmed that the regulations apply only to PHS-supported research activities;
• eliminated the rebuttable presumption of research misconduct when research records fail to adequately document the research being questioned;

• clarified that an institution’s obligation to notify ORI of outcomes in the research misconduct process does not extend to situations in which an institution determines at the inquiry stage, that the investigation is not warranted or finds there was no misconduct. However, cases closed based on admission of misconduct must be reported to ORI regardless of when the admission is made; and

• clarified its intent to require records of research misconduct proceedings to be retained for seven (7) years, notwithstanding some of the concerns raised by commenters.

V. General Policy and Applicability

A. The Final Rule’s Application

The Final Rule applies to each institution that applies for, or receives, PHS support for biomedical or behavioral research, research training, or activities related to that research or research training.\(^7\) Specifically, the Final Rule applies to allegations of research misconduct involving:

• Applications or proposals for PHS support for biomedical or behavioral extramural or intramural research, research training or activities related to that research or research training, including not only original research or clinical trials, but also the operation of tissue and data banks and the dissemination of research information;

• PHS supported biomedical or behavioral extramural or intramural research, or research training programs;

• PHS supported extramural or intramural activities that are related to biomedical or behavioral research or research training; and

• Plagiarism of research records produced in the course of PHS supported research, research training or activities related to that research or research training.

This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for PHS funds resulted in a grant, contract, cooperative agreement, or other form of PHS support.

Institutions are free to devise an alternate system by which to address allegations of misconduct that do not fall within the Final Rule’s definition of research misconduct or that do not involve PHS support.

B. Definition of Scientific Misconduct

Research misconduct is defined as fabrication, falsification, or plagiarism (or “FFP”) in proposing, performing, or reviewing research or in reporting research results.\(^8\) Fabrication is defined as making up data or results and recording or reporting them. Falsification is defined as manipulating research materials, equipment, or processes, or changing or omitting data or results

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\(^7\) 42 C.F.R. § 93.102.
\(^8\) 42 C.F.R. § 93.103.
such that the research is not accurately represented in the research record. Plagiarism is defined as the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.

Research misconduct does not include honest error or differences of opinion. Moreover, research misconduct does not include such things as sloppy science or research practices, authorship disputes, or disagreements based on honest differences of opinion. Additionally, although there may be “misconduct” or actionable conduct in research such as the misuse of federal grant funds, or human subjects protections violations, these types of conduct are regulated not as research misconduct, but rather by other regulatory schemes and guidance documents, i.e., OMB Circulars (A-110, A-122, Appendix E (45 C.F.R. Part 74)), the Common Rule (45 C.F.R. Part 46)), and, for the most part, different agencies, i.e., OHRP, NIH. However, as with research misconduct, violations of these rules may be pursued by the OIG, and/or the DOJ.

This is not to say that research misconduct cannot be pursued under the Federal False Claims Act (31 U.S.C. § 3729 et seq.). See U.S. v. Poehlman, (Dist. Ct. Vt., March 21, 2005 (settling FCA allegations that false data was used in applying for, and renewing, federal research grants). However, much of the enforcement of this type of misconduct relates to pursuit under the research misconduct regulations.

C. Requirements for Finding Misconduct

In order to make a finding of research misconduct, there must be a “significant departure” from accepted practices of the relevant research community; as opposed to the “serious deviation” in the previous regulation. Moreover, the misconduct must have been committed intentionally, knowingly, or recklessly. Again, an honest mistake is not sufficient to support a finding of research misconduct.

D. Proving a Finding of Research Misconduct – the Evidentiary Standard

When evaluating allegations of research misconduct, an institution or HHS finding of research misconduct must be proved by a preponderance of the evidence. A preponderance of the evidence means proof by information and evidence that, when compared with that contrasting it, leads to the conclusion that the facts at issue are more probably true than not.

Consistent with the Office of Science and Technology Policy guidance excluding honest error or difference of opinion from the definition of research misconduct, neither HHS nor the institutions are required to disprove possible honest error or difference of opinion in making a finding of misconduct. Rather, the Respondent may assert these as affirmative defenses that the Respondent has the burden of proving by a preponderance of the evidence. However, institutions and HHS retain the burden of proving research misconduct by a preponderance of the evidence and any admissible, credible evidence the Respondent submits to prove honest error or difference of opinion must be weighed in determining whether the institution and HHS have carried this burden.

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9 42 C.F.R. § 93.103.
10 42 C.F.R. § 93.104.
11 42 C.F.R. § 93.219.
12 42 C.F.R. §§ 93.106(b)(1), (2); 93.516(b).
In satisfying this burden of proof, the institution or HHS may cite the destruction, absence of, or Respondent's failure to provide research records adequately documenting the questioned research as evidence of research misconduct, if the institution or HHS establishes by a preponderance of the evidence that the Respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner and that the Respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.\textsuperscript{13}

Interestingly, in the Proposed Regulation,\textsuperscript{14} HHS proposed that the absence of, or Respondent's failure to provide, research records adequately documenting the questioned research established a presumption of research misconduct that could only be rebutted by credible evidence corroborating the research, or providing some reasonable explanation for the absence of research records. Many commenters expressed concern that there may be plausible, reasonable explanations as to why a researcher may not have research records, such as the Respondent may have no control over the research records that are the subject of the allegation. As such, HHS in the Final Rule eliminated the rebuttable presumption of research misconduct.\textsuperscript{15}

The Respondent also has the burden of proving by a preponderance of the evidence any mitigating factors that are relevant to a decision to impose administrative actions following a research misconduct proceeding.\textsuperscript{16} Such mitigating factors include whether the research misconduct was part of a pattern and practice of activity, did the misconduct have significant impact on the proposed or reported research record, human subjects or other researchers, and/or whether the Respondent accepted responsibility for the misconduct.\textsuperscript{17}

E. Time Limitations

In order to pursue an allegation of research misconduct, the activity must have occurred within six (6) years of the date the HHS or an institution receives an allegation, unless an exception is met.\textsuperscript{18} The exceptions include that if during the years prior to the allegation being received, the Respondent has cited, republished, or otherwise used for his or her potential benefit the research record that is the subject of the allegation of misconduct, this "re-starts" the six year limit.

VI. Institutional Responsibilities

A. General Institutional Compliance Responsibilities

Each institution receiving PHS funds must have written policies and procedures in place for addressing allegations of research misconduct, and the policies must meet the requirements set forth in detail in the Final Rule.\textsuperscript{19} Specifically, the Final Rule sets forth thirteen (13) areas that must be addressed by written policies, including but not limited to:

\begin{itemize}
  \item 42 C.F.R. § 93.106(b).
  \item 70 Fed. Reg. at 28,372.
  \item 42 C.F.R. § 93.106(b)(3).
  \item 42 C.F.R. § 93.408.
  \item 42 C.F.R. § 93.105.
  \item 42 C.F.R. §§ 93.300(a).
\end{itemize}
• Protection of confidentiality of the Respondents, Complainants and research subjects, unless disclosure is otherwise required by law or regulation;

• Written notice to ORI of any decision to open an investigation on or before the date the investigation begins;

• Opportunity for the Respondent to provide written comments on the institution’s inquiry report.

Given that the policy requirements are quite detailed and enumerated, institutions should review the relevant regulation to ensure they have a written policy covering each area.\textsuperscript{20}

In addition to having detailed written policies and procedures, an institution must:

• Respond to each allegation of research in a thorough, competent, objective and fair manner, including ensuring that the institution’s research integrity officer or a member of its oversight committee do not have unresolved personal, professional or financial conflicts of interest with the Complainant, Respondent or witnesses;

• Foster a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct;

• Take 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;

• Provide confidentiality to the extent required by the Final Rule to all Respondents, Complainants, and research subjects identifiable from research records or evidence;

• Take all reasonable and practical steps to ensure the cooperation of Respondents and other institutional members with research misconduct proceedings, including, but not limited to, their providing information, research records, and evidence;

• Cooperate with HHS during any research misconduct proceeding or compliance review;

• Assist in administering and enforcing any HHS administrative actions imposed on its institutional members; and

• Have an active assurance of compliance.\textsuperscript{21}

B. Assurance of Compliance

As noted above, an institution must have on file an Assurance with ORI.\textsuperscript{22} If an institution is too small to handle research misconduct proceedings, it may file a “Small Organization Statement” with ORI instead of filing the formal policies and procedures as required of larger institutions.\textsuperscript{23} In such cases, the small institution must report all allegations of research misconduct

\textsuperscript{20} 42 C.F.R. §§ 93.304(a)-(m).
\textsuperscript{21} 42 C.F.R. § 93.300(a)-(i).
\textsuperscript{22} 42 C.F.R. §§ 93.301-.302.
\textsuperscript{23} 42 C.F.R. § 93.303.
to ORI and ORI, or another appropriate HHS agency, will assist in the development of a process to pursue an allegation of misconduct.

C. Complainant “Whistleblower” Obligations and Protections

A Complainant is responsible for making allegations in good faith, maintaining confidentiality over the proceedings to the greatest extent possible, and cooperating with the Inquiry and/or Investigation. A “good faith” allegation is one in which the Complainant has a belief in the truth of the allegation that a reasonable person in his/her position could have based on information known at the time.24

The institution must take all reasonable and practical efforts to protect the Complainant, which includes monitoring the treatment of those individuals to ensure that they are not retaliated against in the terms and conditions of their employment, or other status within the institution.25

On November 28, 2000, HHS issued a notice of proposed rulemaking to establish regulatory standards for preventing and responding to occurrences of “whistleblower” retaliation, as required by Section 493(e) of the PHS Act.26 These proposed regulations set forth a detailed process for a whistleblower to make a formal retaliation complaint, to pursue an institutional process to determine whether there was retaliation, then to make a formal notice to ORI regarding these issues. As one might imagine, there was industry resistance to such regulation because institutions wanted the flexibility to protect whistleblowers, and pursue actions, in a manner that best fit an institution. As such, the regulations have not been finalized, but the “whistleblower” protections reside, generally, in the research misconduct regulations discussed herein.

D. Confidentiality

Disclosure of the identity of Respondents and Complainants should be limited, to the greatest extent possible, to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding, and as allowed by law.27 However, the institution must disclose the identity of Respondents to ORI as required under the Final Rule. Moreover, to the extent a research misconduct proceeding is the subject of an HHS administrative hearing, these are open to the public.28

Similarly, except as required by law, any records or evidence from which research subjects might be identified must also be kept confidential. Again, disclosure is limited to those who have a need to know to carry out a research misconduct proceeding.29

E. Restoration of the Reputation of the Respondent, Complainant, Witness, Committee Members

An institution must use all reasonable and practical efforts, if so requested and appropriate, to restore the reputation of Respondents, but against whom no finding of research misconduct is

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25 42 C.F.R. § 93.304(l).
27 42 C.F.R. § 93.108(a).
28 42 C.F.R. § 93.517(g).
29 42 C.F.R. § 93.108 (b).
made. This same obligation holds true for the restoration of reputations of Complainants, witnesses, and committee members.

This may be accomplished by notifying individuals who are aware or were involved in the investigation of the final outcome, e.g., witnesses, and publicizing the final outcome in any medium in which the alleged research misconduct was previously publicized, if any. Some institutions remove all record of any allegation of misconduct from any and all files, except the master file of such purged documents is maintained by the Research Integrity Officer to meet the document retention requirements. Other institutions choose not to create only one master file, but rather to place in each file that has a reference to the allegation, a statement that the allegation was found to have no merit.

F. Consortium or Independent Conduct of Research Misconduct Proceeding

An institution is not required to conduct research misconduct reviews internally. Many institutions determine that it either does not have the expertise to conduct such a review, or that the impartiality or objectivity of a well-respected person or group outside of the institution ensures a fairer process. As such, an institution may use the services of a consortium (a group of institutions or professional organizations), or an outside individual to conduct research misconduct proceedings provided that the institution reasonably determines such person(s) to be qualified by practice and experience to conduct research misconduct proceedings.

VII. The Process for Pursuing an Allegation of Research Misconduct

The prescribed process for investigating an allegation of research misconduct involves four general phases:

- Inquiry (see Section VII.A).
- Investigation (see Section VII.B).
- ORI Response (see Section VII.C).
- Respondent’s Appeal Rights (see Section VII.D).

A. The Inquiry

1. Overview

An allegation of research misconduct is generally made to the Institutional Official, who is typically known in institutions as the Research Integrity Officer (“RIO”). In fact, the RIO is generally responsible for overseeing the Inquiry and Investigation process.

In some cases, the RIO may delegate responsibility to conduct the Inquiry and Investigation to an independent party, such as the Corporate Compliance Officer or the Director of Internal Audit. In other cases, these responsibilities will be delegated to outside legal counsel, outside

30 42 C.F.R. § 93.304(k)
31 42 C.F.R. § 93.304(l).
32 42 C.F.R. § 93.306.
consultants or even a consortia. It is important that whoever conducts the review is viewed as independent and impartial so that the results of the process are credible and free from bias.

The Institution must initiate an inquiry (“Inquiry”) if an allegation of research misconduct: (1) meets the definition of “research misconduct”, i.e., FFP; (2) involves PHS support for biomedical or behavioral research, research training or activities related to that research or training; and (3) is sufficiently credible and specific so that potential evidence of research misconduct may be identified.33

An Inquiry is essentially a means of gathering and initial fact finding to determine whether an allegation or apparent instance of misconduct warrants an investigation. As such, an Inquiry does not require a full review of all the evidence.

Institutions may decide, even at the allegation stage, to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding.34 However, it may be more common for an institution to sequester records at the Inquiry stage as it affords the institution time to determine if, in fact, there is a credible reason to confiscate research records in the first place.

2. Notice to the Respondent and Sequestration of Records

At the time of, or before beginning, an inquiry, an institution must make a good faith effort to notify the presumed Respondent in writing of the initiation of a proceeding.35

If it has not already done so at the allegation stage, on or before notifying the Respondent, or before the Inquiry begins, the institution must promptly take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding.36 This involves seizing research notebooks, machine print-outs, data, case report forms, animals or cell lines, computer files, progress reports, journals and the like. The institution must inventory the records and evidence, and sequester them in a secure manner. For example, the institution may make photocopies of all applicable documents and lock the originals in a safe or other secure location.

Although the PHS regulations only stipulate the sequestration occur on or before notifying the Respondent, or before the Inquiry begins, practical advice suggests that materials should be sequestered as soon as possible. It is also prudent to assemble a team of experts, including scientific experts, information systems personnel and others to help identify, take possession of, record, organize and preserve the records. Institutional policies should also specify how and under what circumstances copies of records are provided to the Respondent or the research team so that research can continue.

If, however, the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

33 42 C.F.R. § 93.307(a).
34 42 C.F.R. § 93.305(a).
35 42 C.F.R. § 93.307(b).
36 42 C.F.R. § 93.307(b).
3. **Timing**

The institution must complete the Inquiry within sixty (60) days of its initiation. This includes completing a draft Inquiry Report, as discussed below. There may be circumstances that clearly warrant a longer period. If the Inquiry takes longer, the record must indicate, through written documentation, why it took more than sixty (60) days.37

It is interesting to note that, based on ORI data from 1994-2003, only fifty-nine percent (59%) of the Inquiries that proceeded to Investigations did so within the prescribed time frame.38

4. **Criteria Warranting an Investigation**

The RIO, or his/her delegate, must review the preliminary evidence as gathered through the Inquiry to determine if the allegation warrants an investigation ("Investigation"). The Final Rule provides that an Investigation is warranted if there is:

- A reasonable basis for concluding that the allegation falls 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 Sec. 93.102; and
- Preliminary information-gathering and preliminary fact-finding from the Inquiry indicates that the allegation may have substance.39

5. **Notice to the Respondent and Complainant and Opportunity to Comment**

The institution must notify the Respondent whether the Inquiry found that an investigation is warranted.40 The notice must include a copy of the Inquiry Report and include a copy of, or refer to, this part and the institution's policies and procedures adopted under its Assurance. Generally, a Respondent may be afforded a "reasonable period of time", e.g., thirty (30) days, to comment on the Inquiry Report. The Respondent's comments must be attached to the Report.

The institution may, but is not required to, also notify the Complainant who made the allegation whether the inquiry found that an investigation is warranted.41 The institution may provide relevant portions of the report to the Complainant for comment.

6. **Notice to ORI on a Decision to Open an Investigation**

In the event that the RIO determines, based on the Inquiry, that the allegation of scientific misconduct has merit and an Investigation is warranted, the institution must notify ORI of this

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37 42 C.F.R. § 93.307(g).
38 ORI Closed Investigations into Misconduct Allegations Involving Research Supported by PHS: 1994-2003", by Lawrence J. Rhoades, Ph.D., ORI.
39 42 C.F.R. § 93.307(d).
40 42 C.F.R. § 93.308(a).
41 42 C.F.R. § 93.308(b).
finding, in writing, within thirty (30) days of making such a finding. The institution must also provide ORI with a copy of the Inquiry Report.

7. The Inquiry Report

The written Inquiry Report must include:

- The name and position of the Respondent;
- A description of the allegations of research misconduct;
- The PHS support, including, for example, grant numbers, applications, contracts, and publications listing PHS support;
- The basis for recommending that the alleged actions warrant an investigation; and
- Any comments on the report by the Respondent and Complainant.

ORI may further request that the institution provide information related to:

- The institutional policies and procedures under which the Inquiry was conducted;
- The research records and evidence reviewed, transcripts, or recordings of any interviews, and copies of all relevant documents; and
- The charges for the investigation to consider.

8. Decision Not to Investigate

If the Institution determines that there is not sufficient, credible evidence to pursue an Investigation, the Institution closes the file and need not report such decision to ORI. However, the Institution must keep sufficiently detailed documentation of inquiries to permit a later assessment by ORI of the reasons why the institution decided not to conduct an investigation, upon ORI’s (or other HHS personnel’s) request. As with all research and related records gathered during this process, the institution must keep records in a secure manner for at least seven (7) years after the termination of the inquiry.

B. The Investigation

1. Overview

An Investigation is the formal development of a factual record, and the evaluation of that record, in order to make a finding of whether the Institution believes there was not research misconduct; or was sufficient evidence to make a recommendation for a finding of research

42 42 C.F.R. § 93.309(a).
43 42 C.F.R. § 93.309(a).
44 42 C.F.R. § 93.309(b).
45 42 C.F.R. § 93.316(a).
46 42 C.F.R. § 93.317.
misconduct. In making such a recommendation, the Institution may make recommendations for other appropriate actions, including administrative actions.

2. Notice to ORI of a Decision to Open an Investigation

As noted above, if an Inquiry leads to an Investigation, the Institution must provide ORI with written notice within thirty (30) days of making such finding, and this includes providing, among other things, a copy of the Inquiry Report.

The Investigation regulations reiterate this same thirty (30) day requirement by stating that an Institution must notify the ORI Director of the decision to begin an Investigation, on or before the date the investigation begins, and that the Investigation must begin within this thirty (30) day period. In essence, an Institution must notify ORI of its intention to open an Investigation, and must actually begin the Investigation, within thirty (30) days of concluding the Inquiry Process.

3. Notice to the Respondent

The Institution must notify the Respondent in writing of the allegations within a “reasonable amount of time” after determining that an Investigation is warranted, but before the Investigation begins. There is no regulatory definition of “reasonable period” but may be interpreted to mean within thirty (30) days as long as that time period is practical under the circumstances.

If, as the Investigation proceeds, the Institution identifies other allegations, the Institution must also give the Respondent written notice of any new research misconduct allegations within a reasonable amount of time of deciding to pursue allegations.

4. Process of the Investigation

Documents: Any documents that have not been taken into custody at the allegation or Inquiry stage should be collected and kept secure.

Interviews: The Regulations require that the Institution interview each Respondent, Complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the Investigation. This may include members of the lab, collaborators and witnesses identified by the Respondent. The interviews should be recorded or transcribed, and provided to the interviewee for correction. The recording or transcript should be maintained as part of the Investigation record.

Pursue Leads: Institutions must diligently pursue 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.

47 42 C.F.R. § 93.315.
48 42 C.F.R. §§ 93.310(a), (b).
49 42 C.F.R. § 93.310(c).
50 42 C.F.R. § 93.310(d).
51 42 C.F.R. § 93.310(g).
52 42 C.F.R. § 93.310(h).
Documentation: The Institution must use its best 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 on the merits of the allegations.53

Fair and Impartial Investigation: The Institution must take reasonable steps to ensure an impartial and unbiased Investigation.54 This may require seeking guidance from scientific experts (or including such experts on the investigation team) to best understand the evidence at issue. Other members of the Investigation team may include scientists from outside the institution, forensic scientists to detect evidence tampering, and/or outside counsel or consultants experienced in these types of investigations. All members of the team must be free from any conflict of interest.

5. Notice to the Respondent and Complainant and Opportunity to Comment

The Respondent has the right to review and comment on the draft Investigation Report within thirty (30) days after receiving it. The Institution may also provide the Complainant a copy of the report.

6. Timing

The Investigation must be completed within one hundred twenty (120) days of its initiation.55 This means not only that all interviews, research record reviews, etc., must be completed, but the Investigation Report must be prepared, circulated to the Respondent, and Complainant if the Institution so decides, the Final Report drafted, and the report made to the ORI.

If the Institution provides for an appeal process by which the Respondent may successfully reverse or modify the findings of research misconduct, this process too must be completed within the 120-day time period.56

Note, however, that the Institution may seek an extension from ORI, in writing. ORI may request periodic progress reports when granting extensions.57

It is interesting to note that, based on ORI data from 1994-2003, only thirty-four percent (34%) of the Investigations concluded within the prescribed 120-day time frame, and as much as nineteen percent (19%) took more than three hundred (300) days to reach completion.58

7. The Investigation Report

The Investigation Report must include the following information:59

• The allegations of research misconduct
• PHS support information including grant numbers, etc.

53 42 C.F.R. § 93.310(e).
54 42 C.F.R. § 93.310(f).
55 42 C.F.R. § 93.311(a).
56 42 C.F.R. § 93.314.
57 42 C.F.R. §§ 93.311(b),(c).
58 ORI Closed Investigations into Misconduct Allegations Involving Research Supported by PHS: 1994-2003", by Lawrence J. Rhoades, Ph.D., ORI.
59 42 C.F.R. § 93.313.
• The specific allegations of research misconduct subject to the investigation
• If not already provided, copies of the institutional policies and procedures
• The research records and evidence reviewed, and identify any evidence taken into custody and not reviewed
• Statement of findings which must identify:
  o Whether the misconduct was falsification, fabrication, or plagiarism and if it was intentional, knowing, or in reckless disregard
  o The facts which support the conclusion
  o Whether any publications need correction
  o The person responsible for the misconduct
  o Any current support or known applications or proposals for support that the Respondent has pending with non-PHS Federal agencies
• Any comments made by the Respondent and Complainant

The Institution must maintain and provide, at ORI’s request, all relevant research records and records of the Investigation (including interview notes, etc.).

8. Notice to ORI of the Results of the Investigation

At the conclusion of the Investigation, even if the Institution determines that there was no research misconduct, the Institution must give ORI the following information:\(^{60}\)

• The Investigation Report
• Final institutional action
• A statement as to whether the institution accepts the Investigation’s findings
• A description of any institutional administrative actions

C. Other Institutional Reporting Requirements and Obligations

Before discussing ORI’s responsibilities once it receives the final Investigation Report, there are other institutional obligations that should be identified.

1. Notice to ORI of a Settlement Based on a Confession

An Institution must notify ORI in advance if it intends to close a case at the Inquiry, Investigation, or appeal stage on the basis that: (1) the Respondent has admitted guilt, (2) the parties have reached a settlement with the Respondent; or (3) for any other reason. However, the Institution need not notify the ORI of the closing of a case at the Inquiry stage on the basis that an Investigation is not warranted. (See Section VII.A.8 above).

\(^{60}\) 42 C.F.R. § 93.315.
Once the ORI receives notice of a settlement or closed case, the ORI may consult with the Institution on its basis for closing the case, and the ORI may conduct an oversight review of the Institution's handling of the case and may take appropriate action including:

- Approving or conditionally approving closure of the case;
- Directing the institution to complete its process;
- Referring the matter for further investigation by HHS; or,
- Taking a compliance action.

2. Retention and Custody of Records of Research Misconduct Proceedings

All records related to an Investigation into research misconduct must be kept for a minimum of seven (7) years following the close of the process and any appeals related thereto. The records include any and all interview notes, Inquiry or Investigation Reports, all correspondence with the Respondent, all correspondence with ORI and any and all other documentation related to the process.

3. Immediate Notification of ORI Upon Special Circumstances

At any time during a research misconduct proceeding that an Institution has reason to believe that any of the following conditions exist, it must immediately (i.e., within 24 hours) notify ORI. The conditions warranting such immediate notification include:

- Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
- HHS resources or interests are threatened.
- Research activities should be suspended.
- There is reasonable indication of possible violations of civil or criminal law.
- Federal action is required to protect the interests of those involved in the research misconduct proceeding.
- 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.
- The research community or public should be informed.

4. Institutional Standards

Institutions are not required to apply these Regulations to research not falling within the Regulations' purview. For example, an institution may have other research misconduct review practices (less stringent ones) that track, but do not mimic, the processes defined under the Regulations. Other federal agencies have misconduct in research policies which are applied when

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61 42 C.F.R. § 93.317.
funding from those agencies is involved in an allegation. While much is similar between the policies, including the definition of misconduct in research, there are differences which must be noted.

Conversely, an institution may choose to find conduct to be actionable under its standards even if the action does not meet this part’s definition of research misconduct.\textsuperscript{62} In such cases, the institution may develop its own definition of research misconduct that is broader than the federal definition, and apply the same policy and procedures from an institutional perspective.

D. ORI’s Response to Allegations of Research Misconduct

In addition to learning of research misconduct proceedings through an institution’s reporting of the Inquiry and Investigation, the ORI may also learn of alleged research misconduct from other sources, and in all cases the ORI may respond directly to any allegation of such misconduct at any time before, during, or after an institution’s response. In such cases, the ORI may conduct an allegation assessment, determine if jurisdiction exists, coordinate with other HHS agencies regarding an inquiry and investigation, etc.\textsuperscript{63}

With regard to learning of research misconduct proceedings through the institutions and their Inquiry and Investigation processes as described above, the ORI will review the Institution’s research misconduct proceedings, and in so doing, the ORI may:\textsuperscript{64}

- Determine whether there is HHS jurisdiction under the Final Rule.
- Consider any reports, institutional findings, research records, and evidence.
- Determine if the institution conducted the proceedings in accordance with the Final Rule, in a timely and fair manner, and with sufficient expertise, thoroughness, objectivity, and competence to support the conclusions.
- Obtain additional information or materials from the institution, the Respondent, Complainant, or other persons or sources.
- Conduct additional analyses and develop the evidence.
- Decide whether research misconduct occurred, and, if so, who committed it.
- Make appropriate research misconduct findings and take any other actions necessary to complete the review.

1. Possible ORI Responses Based Upon Its Review

After completing its review, (a review initiated through an Institution’s provision of an Investigation Report, or a review arising out of an ORI initiated investigation) ORI may close the case if ORI decides that research misconduct did not occur, or may make findings of research misconduct, and seek HHS approval of proposed administrative actions.

\textsuperscript{62} 42 C.F.R. § 93.319.
\textsuperscript{63} 42 C.F.R. § 93.400.
\textsuperscript{64} 42 C.F.R. § 93.403.
The ORI may also recommend that HHS seek to settle the case.\textsuperscript{65} This might include a process wherein HHS would contact the Respondent and work out a “deal” which would include some form of punishment for the Respondent (e.g., fines, debarment, etc.).

Upon receiving HHS approval of the administrative actions, the ORI notifies the Respondent by sending a charge letter by certified mail or private delivery service to the last known address of Respondent or the last known principal place of business of the Respondent’s attorney. However, if debarment or suspension from eligibility for federal financial assistance is proposed, the HHS debarring official issues the notice for that action as part of the charge letter.\textsuperscript{66}

Note that the ORI also may notify and consult with other offices at any time if it has reason to believe that a research misconduct proceeding may involve that office. Specifically, if ORI believes that a criminal or civil fraud violation may have occurred, it shall promptly refer the matter to the DOJ or OIG, or other appropriate investigative body. ORI may provide expertise and assistance to the DOJ, OIG, PHS offices, other Federal offices, and state or local offices involved in investigating or otherwise pursuing research misconduct allegations or related matters.\textsuperscript{67}

2. **Possible HHS Administrative Actions to Sanction Research Misconduct**

In general, some of the possible outcomes of a finding of scientific misconduct include debarment, suspension, letters of reprimand, restriction on research activities, termination of grants, and more (as discussed below). In significant cases, HHS may also seek to recover PHS funds spent in support of activities that involved research misconduct. In making such determinations of administrative actions, HHS will take into account whether the actions were knowing or reckless, whether the actions were part of a pattern or practice of wrongdoing, the impact of the misconduct, the Respondent’s acceptance of responsibility, and other mitigating circumstances.

Pursuant to the governing regulations, HHS may impose administrative actions in response to a research misconduct proceeding, that include, but are not limited to.\textsuperscript{68}

- Clarification, correction, or retraction of the research record.
- Letters of reprimand.
- Imposition of special certification or assurance requirements to ensure compliance with applicable regulations or terms of PHS grants, contracts, or cooperative agreements.
- Suspension or termination of a PHS grant, contract, or cooperative agreement.
- Restriction on specific activities or expenditures under an active PHS grant, contract, or cooperative agreement.
- Special review of all requests for PHS funding.
- Imposition of supervision requirements on a PHS grant, contract, or cooperative agreement.

\textsuperscript{65} 42 C.F.R. § 93.404.
\textsuperscript{66} 42 C.F.R. § 93.405(a).
\textsuperscript{67} 42 C.F.R. § 93.401.
\textsuperscript{68} 42 C.F.R. § 93.407.
• Certification of attribution or authenticity in all requests for support and reports to the PHS.
• No participation in any advisory capacity to the PHS.
• Adverse personnel action if the Respondent is a Federal employee, in compliance with relevant Federal personnel policies and laws.
• Suspension or debarment under 45 CFR Part 76, 48 CFR Subparts 9.4 and 309.4, or both.

The purpose of the HHS administrative actions is remedial. As such, the administrative action taken should be commensurate with the seriousness of the misconduct. HHS will consider aggravating and mitigating factors in determining the appropriate administrative action. These factors include consideration of the following:\(^69\)

- Were the Respondent’s actions knowing or intentional, or was the conduct reckless?
- Was the research misconduct an isolated event or part of a continuing or prior pattern of dishonest conduct?
- Did the misconduct have a significant impact on the proposed or reported research record, research subjects, other researchers, institutions, or the public health or welfare?
- Has the Respondent accepted responsibility for the misconduct by: (1) Admitting the conduct? (2) Cooperating with the research misconduct proceeding? (3) Demonstrating remorse and awareness of the significance and seriousness of the research misconduct? and, (4) Taking steps to correct or prevent the recurrence of the research misconduct?
- Does the Respondent blame others rather than accepting responsibility for the actions?
- Did the Respondent retaliate against Complainants, witnesses, committee members, or other persons?
- Is the Respondent presently responsible to conduct PHS supported research?
- Are there other factors appropriate to the circumstances of the particular case?

3. Final HHS Action

There are several ways that an HHS action may become final, depending on whether the Respondent pursues his/her appeal rights, or not.

If the Respondent does not contest the charge letter by requesting a hearing within the thirty (30) day period as provided for in the regulations, the finding of research misconduct becomes final, and the proposed administrative actions become final.\(^70\)

\(^69\) 42 C.F.R. § 93.408.
\(^70\) 42 C.F.R. § 93.406.
If HHS recommends a settlement, the decision is final upon the approval by both parties of a settlement agreement containing the findings and the administrative actions. The settlement agreement may provide that the Respondent does not admit wrongdoing, but rather that the Respondent is settling the action to avoid protracted litigation. Settlement agreements are publicly available regardless of whether the ORI made a finding of research misconduct.

If the Respondent initiates appeal proceedings, i.e., an ALJ appeal, actions become final after this process is complete. These appeal rights are discussed below.

E. Respondent’s Appeal Rights

1. Overview

Clearly the ramifications of engaging in research misconduct are grave for those individuals involved, and for their institutions. Respondents have appeal rights (even appeals to federal district court); however, the process can be extremely costly and time intensive. Perhaps even more problematic is the damage to reputation and career that can result from an allegation of scientific misconduct.

2. Respondent May Request an ALJ Hearing

Respondents have the opportunity to contest findings of research misconduct by requesting a hearing within thirty (30) days of receipt of the charge letter or other written notice. The Respondent’s request must be: in writing, signed by the Respondent or Respondent’s attorney and sent by certified mail or other equivalent method to the Departmental Appeals Board (“DAB”). The request for the hearing must admit or deny the finding of scientific misconduct, provide detailed reasons for each denial or challenge, identify all defenses, and identify any mitigating factors.

The DAB will assign an ALJ, and within thirty (30) days of receiving a request for a hearing, there will be a decision about whether the requested hearing should be granted. The hearing will be before an ALJ, as opposed to the three (3) person panel of the DAB as was the process prior to the Final Rule.

The ALJ must grant a hearing if the ALJ determines that there is a genuine dispute over facts material to the research misconduct findings, or the proposed administrative actions, including any debarment or suspension. If the Respondent simply asserts error for each finding, or states a general denial to the allegations in the charge letter, this is not sufficient to establish genuine dispute and as such the ALJ need not grant a hearing.

3. Respondent’s Appeal Process

The Final Rule sets forth a detailed hearing process that is modeled on the HHS OIG regulation, 42 CFR part 1005, including provisions related to ex parte communications, discovery, witness lists, pre-hearing conferences, etc. Given that these regulations are so detailed, we describe

71 42 C.F.R. § 93.409.
72 42 C.F.R. § 93.501.
73 42 C.F.R. § 93.502(a).
74 42 C.F.R. § 93.503(a).
the process in broad terms and parties to such a process should carefully review the requirements as set forth in the regulations.

If a hearing is granted, the ALJ may appoint a scientific expert to assist in the process. The parties may put forth names for an expert, but if the parties cannot agree, the ALJ will pick the expert and s/he must be accepted by the parties. The hearing may be in-person, or the right to such in-person hearing may be waived by the Respondent.

A hearing is not limited to the findings and evidence set forth in the charge letter or the Respondent’s request for a hearing. In other words, the ALJ will review the matter on the merits, and s/he is not limited by the evidence or record created below. As such, additional evidence and information may be offered at the hearing by either party unless the offered evidence is:

- Privileged, including but not limited to those protected by the attorney-client privilege, attorney-work product doctrine, or Federal law or regulation.
- Otherwise inadmissible under as determined by the ALJ.
- Not offered within the times or terms set forth in the regulations regarding limits on discovery, submission of witness statements and the like.

In the hearing with the ALJ, the ORI has the burden of proof of scientific misconduct by the preponderance of the evidence, i.e., that it is more likely true than not that the Respondent committed research misconduct. The ALJ oversees the hearing in its entirety including the use of witnesses and experts and all evidence presented. The ALJ shall issue a ruling in writing setting forth proposed findings of fact and any conclusions of law within sixty (60) days after the last submission by the parties in the case. However, the ALJ may miss this deadline, in which case s/he must promptly set a new deadline and notify all parties.

The ALJ’s findings of fact and conclusions of law constitute a recommended decision to the Assistant Secretary for Health (“ASH”). (This is opposed to the old rules under which the DAB panel’s decision constituted the final agency action). The ASH may let the ALJ’s recommended decision stand, or it may modify or reject the ALJ’s decision, if it is found to be arbitrary and capricious, or clearly erroneous. If the ASH is going to review the ALJ’s decision, it must notify the parties of its intention to do so within thirty (30) days after service of the recommended decision. Again, if that notification is not provided within this time period, the ALJ’s recommended decision becomes final.

If debarment or suspension from eligibility for Federal financial assistance and/ or contracts is proposed, the decision of the ALJ or of the ASH, as the case may be, constitutes proposed findings of fact to the HHS Debarring Official. If the ASH takes final action on the ALJ’s recommended decision and the Debarring Official concurs, the ASH decision constitutes final agency action.

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75 42 C.F.R. § 93.502(b).
76 42 C.F.R. § 93.503(d).
77 42 C.F.R. §§ 93.515, 93.519.
78 42 C.F.R. §§ 93.512, 93.513, 93.517(c).
79 42 C.F.R. § 93.523.
80 42 C.F.R. § 93.523.
The Respondent may appeal the ALJ’s (or ASH’s) decision to the federal district court. However, these actions take a great deal of time and are very costly but provide another appeal option for those Respondents who believe they are wrongly accused.

VIII. Institutional Compliance Issues

Institutions must foster a research environment that discourages misconduct in all research and that deals forthrightly with possible misconduct associated with PHS supported research.\textsuperscript{81}

A. ORI’s Basis for Decisions of Institutional Non-Compliance

ORI may decide that an institution is not compliant with the research misconduct regulations if the institution shows a disregard for these requirements and its Assurance. In making this decision, ORI may consider the following factors:

- Failure to establish and comply with policies and procedures under this part;
- Failure to respond appropriately when allegations of research misconduct arise;
- Failure to report to ORI all investigations and findings of research misconduct under this part;
- Failure to cooperate with ORI's review of research misconduct proceedings; or
- Other actions or omissions that have a material, adverse effect on reporting and responding to allegations of research misconduct.\textsuperscript{82}

B. HHS’s Institutional Compliance Actions

An institution’s failure to comply with its Assurance and the research misconduct regulations may result in enforcement action against the institution.\textsuperscript{83} ORI notes, however, that it would first provide advice and assistance to the institution to enhance its processes.\textsuperscript{84}

However, if an institution fails to comply with its assurance and the requirements of this part, HHS may take some or all of the following compliance actions:

- Issue a letter of reprimand.
- Direct that research misconduct proceedings be handled by HHS.
- Place the institution on special review status.
- Place information on the institutional noncompliance on the ORI Web site.
- Require the institution to take corrective actions.
- Require the institution to adopt and implement an institutional integrity agreement.
- Recommend that HHS debar or suspend the entity.

\textsuperscript{81} 42 C.F.R. § 93.412(a).
\textsuperscript{82} 42 C.F.R. § 93.412(b).
\textsuperscript{83} 42 C.F.R. § 93.413(a).
\textsuperscript{84} 70 Fed. Reg. at 28,380.
- Any other action appropriate to the circumstances.\textsuperscript{85}

If the institution’s actions constitute a substantial or recurrent failure to comply with the misconduct regulations, ORI may also revoke the institution’s Assurance. Finally, ORI may make public any findings of institutional noncompliance and HHS compliance actions.\textsuperscript{86}

\section*{IX. Cases}

\subsection*{A. The Historic Perspective}

There is one primary incident that heightened the sensitivities of the research community, and perhaps the public at large, to research misconduct issues. This is the “Baltimore” case. There are books,\textsuperscript{87} scholarly works and scores of articles dissecting this case in great detail. Given the lengthy saga with its many twists and turns, we set forth only the essential elements of the case here.

A postdoctoral fellow, Margot O’Toole, worked in the laboratory of Dr. Imanishi-Kari, a then assistant professor at MIT’s Center for Cancer Research. During her tenure under Imanishi-Kari, O’Toole was unable to reproduce lab results in her own experimental mice, which led her to review the laboratory notebooks containing Dr. Imanishi-Kari’s underlying data. She concluded that the data on seventeen (17) pages were inconsistent with the data in the contested Cell paper by Dr. Imanishi-Kari, and she made allegations of research misconduct.

Enter David Baltimore, a Nobel Prize laureate with whom Dr. Imanishi-Kari co-wrote the 1986 scientific paper at issue. Although Dr. Baltimore was not accused of fabrication, he staunchly defended the paper, and Dr. Imanishi-Kari, a position which cost him quite a bit. In fact, this event caused him to step-down as the President of Rockefeller University under a cloud of question.

There were three different investigations, including one at MIT and one conducted by an NIH-appointed panel. In each instance, the conclusions were that there were minor errors that were corrected, but that there was no support for a claim of misconduct.

The saga did not end here. O’Toole, through other laboratory personnel, reached out to two (2) NIH researchers (Ned Feder and Walter Stewart), who were known in the research community as avid pursuers of perceived fraud. Their involvement elevated the discourse and captured the attention of Representative John D. Dingell who pressed for congressional hearings on the subject. The hearings focused on what the Representative determined to be fraud in federally-funded research, with particular animosity directed at Dr. Baltimore. The House Committee called for a Secret Service investigation into Dr. Imanishi-Kari’s lab notebooks, and other information and evidence. The investigation concluded in a finding that Dr. Imanishi-Kari had falsified data and engaged in research misconduct. Premised largely on this finding, in 1991, NIH’s Office of Scientific Integrity accused her of falsifying data, and recommended that she be barred from receiving federal research grant funds for ten (10) years.

Helpfully for Dr. Imanishi-Kari, the HHS Office of Scientific Integrity was reorganized in 1992, and became what is known today as ORI. As part of this reorganization and reauthorization,

\textsuperscript{85}42 C.F.R. § 93.413(c).
\textsuperscript{86}42 C.F.R. §§ 93.413(d), (e).
\textsuperscript{87}THE BALTIMORE CASE: A TRIAL OF POLITICS, SCIENCE, AND CHARACTER, by Daniel J. Kevles.
there was an appellate procedure established, of which Dr. Imanishi-Kari availed herself. Specifically, a three-person appeals panel reviewed ORI’s report of a finding of scientific misconduct as to Dr. Imanishi-Kari, and concluded that the finding was in error. The panel dismissed the case against Dr. Imanishi-Kari, thus exonerating her and Dr. Baltimore, and there endeth the saga . . . or does it?

B. More Recent Cases

Many more recent, and very high profile, cases are arising based on allegations of scientific misconduct. Below we highlight some cases from recent years that may be of interest.

1. Vipul Bhrigu

Vipul Bhrigu, a former postdoctoral fellow at the University of Michigan, was debarred in April 2011 for three years from any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement programs of the United States Government, and from serving in any advisory capacity to the PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant. Bhrigu was caught on videotape sabotaging the experiments of a graduate student in his lab at the university last year. He admitted that he “was trying to slow the student down.” He was fired and taken to court, where he pleaded guilty to malicious destruction of property. He was subsequently ordered to pay more than $30,000 total in fines and restitution.

2. Philippe Bois

Philippe Bois, former postdoctoral fellow in the Department of Biochemistry at St. Jude Children's Research Hospital, was found to have knowingly and intentionally falsified data reported in two (2) research papers - the products of research funded by five (5) NIH grants. For three (3) years beginning in January 2008, Mr. Monte was debarred from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government and prohibited from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

3. Meleik Goodwill

Meleik Goodwill, a former postdoctoral fellow at Wadsworth Center, a research laboratory at the New York State Department of Health, was found guilty of fabricating data for growth curves and using unrelated western blot images in a 2007 Journal of Neuroimmunology article. The article was subsequently retracted in 2008. Goodwill, who entered into a Voluntary Settlement Agreement in January 2011, will still be allowed participate in PHS-supported research, but only with an ORI-approved supervisory plan to ensure the integrity of her work over the next three (3) years. Additionally, Ms. Goodwill is excluded from service in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of three (3) years, beginning in January 2011.

88 http://ori.dhhs.gov/misconduct/cases/Bhrigu_Vipul.shtml
89 http://ori.dhhs.gov/misconduct/cases/Bois_Philippe.shtml
90 http://ori.dhhs.gov/misconduct/cases/Goodwill_Meleik.shtml
4. **Jayant Jagannathan**

Jayant Jagannathan, former Resident Physician at University of Virginia Medical Center, engaged in research misconduct by plagiarizing PHS-funded research in five (5) publications, where he plagiarized large amounts of text and an illustration taken from other publications supported by NIH grant awards. Jagannathan entered into a Voluntary Settlement Agreement, where for a period of four (4) years, beginning in October 2011, he will be required to have an ORI-approved supervisory plan in place to ensure the integrity of his work in PHS-supported research, as well he will be excluded from service in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant. Additionally, Mr. Jagannathan will also be required to submit a letter to the editor of the journal, Neurosurgical Clinics of North America, requesting that one of the five (5) papers in question be retracted because he had plagiarized portions of text reported in it; the letter must be sent to ORI for approval prior to being sent to the editor.

5. **Marija Manojlovic**

Marija Manojlovic, a former graduate student at the University of Pittsburgh, falsified data in a poster presentation and in a draft paper submitted for publication. She was found guilty of research misconduct after an inquiry was conducted and written admission obtained by the University of Pittsburgh, and additional analysis conducted by ORI in its oversight review. Manojlovic entered into a Voluntary Settlement Agreement for a period of three (3) years, beginning in September 2011. Like the prior two cases, Manojlovic will be required to have an ORI-approved supervisory plan in place to ensure the integrity of her work in PHS-supported research, as well she will be excluded from service in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

6. **PPS Clinical Research LLC**

PPS Clinical Research, a St. Louis-based multi-specialty clinical trial management company, was found by the FDA in 2010 to have falsified records about multiple patient exams that never occurred, and failed to properly store investigational drug. While PPS is not an academic medical center or teaching hospital, and the research was not funded by PHS, this case highlights an issue that is relevant to all institutions who participate in clinical trials. Specifically, the FDA noted conflicts between what patients reported about “their interactions with PPS versus what PPS’ patient records purported to document.” PPS contracted with the German drug manufacturer Boehringer Ingelheim to test a drug dubbed the “female Viagra.” The case originated when PPS staffers reported to the drug manufacturer in 2009 that a fellow study coordinator falsified patient visits; Boehringer Ingelheim reported it to the FDA five days later. Boehringer Ingelheim announced that it was discontinuing the development of the drug less than four months after the FDA’s reproductive health advisory committee voted 10-1 in June 2010 that the drug was not significantly more effective than a placebo. PPS plead guilty in December 2011 to a federal felony charge of obstructing the FDA’s 2010 investigation and agreed to a $68,000 fine and to forfeit $7,000. Without admitting liability, PPS also agreed to pay $206,000 in the civil settlement.

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92 [http://ori.dhhs.gov/misconduct/cases/Manojlovic_Marija.shtml](http://ori.dhhs.gov/misconduct/cases/Manojlovic_Marija.shtml)
7. **Scott E. Monte**

Scott E. Monte, former Clinical Research Associate at Huntington Memorial Hospital was found to have knowingly and intentionally: (1) entered falsified and fabricated information on five research protocol case report forms; (2) falsified an examination report in a physician's progress note and entered the falsified document in the patient's research chart; and (3) fabricated progress notes for four patients and a case report form for one of these patients. For three (3) years beginning in January 2008, Mr. Monte was debarred from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government and prohibited from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

8. **Jon Sudbø**

Jon Sudbø, a former doctoral student and faculty member, University of Oslo, and former physician in the Department of Medical Oncology and Radiotherapy, NRH, was excluded permanently, beginning in August 2007, from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government and from serving in any advisory capacity to PHS. Dr. Sudbø falsified and fabricated research in a grant application and a progress report for the funded grant.

9. **United States v. Poehlman**

Eric Poehlman, a researcher with federal funds, pled guilty in March 2005 to making material false statements in 17 research grant applications, will pay $180,000 to settle a civil complaint related to false grant applications, will pay $16,000 in attorney's fees to the qui tam relator, will be barred for life from seeking or receiving funding from any federal agency in the future, and must submit letters of retraction and correction to at least 10 scientific journals. This was a Federal False Claims Act case brought by a relator, who was a former research assistant of Poehlman's.

10. **United States v. Kornak**

Paul H. Kornak, a Stratton Veterans Affairs Medical Center former research assistant, was sentenced in January 2005 to nearly six years in prison and ordered to pay over $600,000 in restitution for criminally negligent homicide and other crimes, in connection with the falsification of patient records. Kornak admitted to falsifying documents in order to qualify James J. DiGiorgio for a cancer drug study. DiGiorgio would not have otherwise qualified for the study because of his impaired kidney and liver function. DiGiorgio was enrolled in the study based on the false documents, was given the chemotherapeutic drugs and died less than two weeks later. Kornak also was excluded for life from participating in any and all Federal agency transactions, both procurement and nonprocurement.

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93 http://edocket.access.gpo.gov/2008/E8-1024.htm
A comprehensive list of ORI findings of research misconduct and administrative actions from 2003-2007 can be found at http://ori.dhhs.gov/ misconduct/cases.

X. Conclusion

Research misconduct hurts science overall. It diminishes the public’s trust in researchers, and more specifically in human subjects’ willingness to participate in research. This further limits an already constrained population of participants. Moreover, when underlying research is tainted by misconduct, further research which builds upon such studies is also tainted and could, in fact, lead to harm for subjects of future studies. For these and other valuable purposes, it is critical to train researchers and other professionals as to their obligations in this arena to place your institution in the best position to avoid any allegations, much less findings, of research misconduct.