

Findings of Research Misconduct

Notice Number: NOT-OD-18-216

Key Dates

Release Date: August 10, 2018

Related Announcements

None

Issued by

National Institutes of Health ([NIH](#))

Purpose

SUMMARY: Notice is hereby given that on July 13, 2018, the U.S. Department of Health and Human Services (HHS) Debarring Official, on behalf of the Secretary of HHS, issued a final notice of debarment based on an Administrative Law Judge's findings of research misconduct against Christian Kreipke, Ph.D., former Research Associate Professor, Wayne State University. Dr. Kreipke engaged in research misconduct in research supported by National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH), grants R01 NS039860 and R01 NS064976-01A2. The administrative actions, including five (5) years of debarment, were implemented beginning on July 13, 2018, and are detailed below.

FOR FURTHER INFORMATION CONTACT:

Wanda K. Jones, Dr.P.H., Interim Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453-8200.

SUPPLEMENTARY INFORMATION:

Christian Kreipke, Ph.D., Wayne State University: ORI issued a charge letter enumerating findings of research misconduct and proposing HHS administrative actions. Dr. Kreipke ("Respondent") subsequently requested a hearing before an Administrative Law Judge (ALJ) of the Departmental Appeals Board to dispute these findings. A hearing before the ALJ was held on July 10-12, 2017. On May 31, 2018, the ALJ issued his recommended decision, finding that Respondent recklessly caused or permitted twenty-three (23) instances of research misconduct in his three (3) grant applications, two (2) articles on which he was the first listed author, and two (2) posters on which he was the first listed author. The ALJ held that appropriate administrative actions included a five-year debarment from any contracting or subcontracting with any agency of the United States and from eligibility for or involvement in nonprocurement programs of the United States.

referred to as “covered transactions.” 2 CFR parts 180 and 376. The ALJ held it was an appropriate administrative action to also impose a five-year prohibition from serving in any capacity to the U.S. Public Health Service (PHS), including but not limited to, service on any PHS advisory committee, board, or peer review committee, or as a consultant. The ALJ noted that ORI also had proposed that the publisher of certain articles be notified of the need to retract those articles and that retraction had already occurred by the time of his recommended decision.

Under the regulation, the ALJ's recommended decision went to the Assistant Secretary for Health, who did not modify it and forwarded it to the HHS Debarring Official, who is the deciding official for the debarment. The ALJ decision constituted the findings of fact to the HHS Debarring Official in accordance with 2 CFR 180.845(c). On July 13, 2018, the HHS Debarring Official issued a final notice of debarment to begin on July 13, 2018, and end on July 12, 2023.

Respondent's grant applications, articles, and posters in question examined the differential effects of endothelin receptor antagonists on traumatic brain injury-induced hypoperfusion of cerebral blood flow, neuronal cell injury, and cognition in rat animal models.

Respondent recklessly included falsely described images in the following grant applications:

- R01 NS064976-01A1 submitted to NINDS, NIH (unfunded)
- R01 NS064976-01A2 submitted to NINDS, NIH (funded)
- R01 NS065824-01 submitted to NINDS, NIH (unfunded)

Respondent recklessly included falsely described images in the following publications and posters:

- “Differential effects of endothelin receptor A and B antagonism on cerebral hypoperfusion following traumatic brain injury.” *Neurological Research* 32(2):209-14, 2010 Mar (“NR2010”). Retracted in *Neurological Research* 39(5):472, 2017 May.
- “Clazosentan, a novel endothelin A antagonist, improves cerebral blood flow and behavior after traumatic brain injury.” *Neurological Research* 33(2):208-13, 2011 Mar (“NR2011-1”). Retracted in *Neurological Research* 39(5):472, 2017 May.
- 2009 poster for a Department of Veterans Affairs (VA) presentation: “Using endothelin-A antagonists to ameliorate hypoperfusion and cognitive deficits following brain trauma: towards a clinical trial” (“VA2009”).

- 2010 poster for a VA presentation: “Endothelin-1 receptor A antagonists improve neurologic and cognitive outcome following TBI” (“VA2010”).

The following findings of research misconduct were proven by a preponderance of the evidence. Respondent recklessly included:

- falsely described Fluoro-Jade stained images of rat brain cells in:

--Figure 8 (left panel) in R01 NS064976-01A1

--Figure 8B (left panel) in R01 NS064976-01A2

--Figures 4A-F in R01 NS065824-01

--Figure 3 (right and left panels) in NR2011-1

--Figure 5C in NR2010

--Figure 3 (panel 3) and Figure 6 (right and left panels) in VA2009

--Figure 3 (panel 3) and Figure 6 (right and left panels) in VA2010

- falsely described systolic blood pressure curves in Figures 4A and 4B in NR2010

- falsely described cerebral blood flow graphs in:

--Figure 5 (left panel) in R01 NS064976-01A1

--Figure 5 (left panel) in R01 NS064976-01A2

--Figure 3A in NR2010

--Figure 5 in VA2009

--Figure 5 in VA2010

- falsely described Western blot images in one of the following three grant applications (because at least one of the three must be false): Figure 1 (me+TBI panel for VEGF) in R01 NS065824-01, Figure 2B in R01 NS064976-01A1, and Figure 2B in R01 NS064976-01A2

- falsely described Western blot images in:

--Figure 2A in R01 NS064976-01A1

--Figure 2A in R01 NS064976-01A2

- a falsely described image of lectin labeled rat brain section in Figure 2C in R01 NS065824-01

Thus, the research misconduct findings set forth above became effective, and the following administrative actions have been implemented for a period of five (5) years, beginning on July 13, 2018:

(1) Dr. Kreipke is 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 referred to as ``covered transactions' pursuant to HHS' Implementation (2 CFR part 376) of Office of Management and Budget (OMB) Guidelines to Agencies on overnmentwide Debarment and Suspension (2 CFR part 180); and

(2) Dr. Kreipke is 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.

Inquiries

Please direct all inquiries to:

Wanda K. Jones
Office of Research Integrity
Telephone: 240-453-8200

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Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Office of Research Integrity,
U.S. Department of Health and Human Services,

v.

Christian Kreipke, Ph.D.

Respondent.

Docket No. C-16-402

Decision No. CR5109

Date: May 31, 2018

RECOMMENDED DECISION

This is a recommended decision of an administrative law judge (ALJ) to the Assistant Secretary for Health pursuant to 42 C.F.R. § 93.523(a).¹ This decision becomes final after 30 days if the Assistant Secretary for Health does not notify the parties of an intention to review this recommended decision within 30 days of the date of service of this decision, which is the date of this decision. 42 C.F.R. § 93.523(b). Debarment is recommended, therefore, pursuant to 42 C.F.R. § 93.523(c), the Assistant Secretary for Health will serve a copy of the decision upon the debarring official; the decision constitutes findings of fact to the debarring official; and the debarring official's decision on the recommended debarment will be the final agency action on debarment. 42 C.F.R. § 93.523(c).

The following findings and conclusions are recommended based upon the findings of fact, conclusions of law, and analysis in this decision.

¹ Citations are to the 2015 revision of the Code of Federal Regulations (C.F.R.), unless otherwise stated. The 2015 revision is cited as that revision was in effect on February 10, 2016, when the Office of Research Integrity (ORI) notified Respondent of charges of research misconduct.

1. Respondent, Christian Kreipke, Ph.D., recklessly caused or permitted 23 instances of research misconduct in his grant applications, articles on which he was the first listed author, and two posters on which he was the first listed author.
2. Appropriate administrative actions are:
 - a. Five-year debarment from any contracting or subcontracting with any agency of the United States and from eligibility for, or involvement in, nonprocurement programs of the United States referred to as “covered transactions.” 2 C.F.R. pts. 180 and 376.
 - b. Five-year prohibition from serving in any capacity to the Public Health Service (PHS), including but not limited to, service on any PHS advisory committee, board, or peer review committee, or as a consultant.
 - c. ORI also proposed that the publisher of certain articles be notified of the need to retract those articles. Retraction has already occurred.

I. Procedural History

ORI notified Respondent by letter dated February 10, 2016, of charges of research misconduct, administrative actions, and debarment. ORI alleges that the research misconduct occurred during a 5-year period and included 64 instances of using falsified images in 6 unfunded and 1 funded National Institute of Health (NIH) grant applications, 3 publications, 5 posters, and 1 book. Specific administrative actions proposed included debarment for ten years from contracting with any federal agency and from eligibility for or involvement with nonprocurement programs of the federal government; prohibition from serving in any advisory capacity to the PHS, including any PHS advisory committee, board, or peer review committee or as a consultant for ten years; and required retraction of three papers published in 2010 and 2011, in the journal *Neurological Research*. ORI Exhibit (Ex.) 67 at 2-3.

Respondent filed a request for hearing on March 8, 2016, that was received at the Departmental Appeals Board (DAB), Civil Remedies Division (CRD) on March 9, 2016 (RFH). The case was assigned to me on March 25, 2016, for hearing and a recommended decision. A Notice of Case Assignment and Appointment of Administrative Law Judge; Notice of Prehearing Conference; and Prehearing Case Development Order (Prehearing Order) was issued on March 25, 2016 and amended on March 31, 2016. A prehearing conference was convened by telephone on April 20, 2016, which was recorded and made available to the parties. On April 29, 2016, I issued a ruling accepting Respondent’s request for hearing, ordered further case development, and set the case for a final prehearing conference, and trial beginning July 10, 2017 and continuing through July 14, 2017.

ORI filed a motion for summary judgment on August 22, 2016 with ORI Exs. 1 through 73. Respondent filed a response in opposition to the ORI motion on September 21, 2016 with Respondent's exhibits (R. Exs.) 1 through 11 which were refiled on September 30, 2016 and again on October 5, 2016. Respondent filed an additional exhibit on October 4, 2016, incorrectly marked R. Ex. 1. On April 7, 2017, Respondent filed a motion for leave to file with exhibits informing me of the March 10, 2017 initial decision of an administrative judge (AJ) sitting for the Merit Systems Protection Board in a case brought by Respondent against the U.S. Department of Veterans Affairs (VA). The case concerned Respondent's termination by the VA and alleged retaliation for Respondent's whistleblower activity. The AJ found jurisdiction under the Whistleblower Protection Act and granted Respondent's request for corrective action. ORI filed ORI Ex. 74 on May 11, 2017. Respondent filed R. Exs. 15, 23, 29, and 30 on May 16, 2017. Respondent filed R. Exs. 14, 21, 28, and 29 on May 18, 2017. On June 14, 2017, I denied the ORI motion for summary judgment.

On June 16, 2017, ORI filed objections to Respondent's proposed exhibits. Respondent refiled his exhibits marked R. Exs. 1 through 14 on June 20, 2017. A telephonic prehearing conference was convened on June 23, 2017, the recording of which was made available to the parties. Respondent refiled his exhibits marked R. Exs. 1 through 30 on June 29, 2017. On July 6, 2017, Respondent filed a document that purports to be the transcript of an interview of Justin Graves on November 1, 2012 (Departmental Appeals Board Electronic Filing System (DAB E-File) Item # 45). The document is not properly marked as an exhibit, it was not offered as evidence, and is not considered for any purpose as I cautioned the parties during the final prehearing conference and in the Prehearing Order ¶ III.C.4.b. Transcript (Tr.) 59-61, 67-70.

A hearing was convened July 10 through 12, 2017. A transcript of the three-day hearing was prepared and made available to the parties. ORI Exs. 1 through 74² were admitted. Tr. 21-23. R. Exs. 1 through 26, and 29 through 31³ were admitted. Tr. 24-58, 344, 632-34. ORI called the following witnesses: Alexander P. Runko, Ph.D. (Tr. 82-95), and Philip R. Cunningham, Ph.D. (Tr. 102- 93). Respondent testified (Tr. 232-99, 349-615, 635-833) and also called Justin Graves (Tr. 206-30) and Anca Vlasopolos, Ph.D. (Tr. 315-347) as rebuttal witnesses.

² ORI exhibits admitted and considered as evidence correspond to the following DAB E-File Item #'s: 11d through 11w, 12, 12a through 12s, 13, 13a through 13s, 14, 14a through 14l, and 24.

³ Respondent's exhibits admitted and considered as evidence correspond to the following DAB E-File Item #'s: 39a through 39v, 39x, 39a3, 41, 43a, 43b, 43d and 47.

On July 11 and 12, 2017, during the hearing, Respondent filed motions to complete the record. Respondent offered without objection from ORI, the document referred to in the Wayne State University final report of investigation (WSU Investigation) (ORI Exhibit 1) as Exhibit 48 titled “Kropinski, Graves, Cantazaro testimony 082311.Full.pdf.” Tr. 621-23; ORI Ex. 1 at 43. Respondent did not mark the document (DAB E-File Item # 47) as an exhibit. However, the document is treated as marked R. Ex. 31, and it was admitted as such at hearing without objection. Tr. 632-34.

On July 25, 2017, Respondent filed a motion to complete the record. ORI Ex. 18 is an extract from “Cerebral Blood Flow, Metabolism, and Head Trauma,” published in 2013 of which Respondent was a co-editor. Respondent requested leave, without objection by ORI, to have the entire book included in the record. Tr. 449-54. Respondent filed a copy of the book (DAB E-File Item # 49a) but failed to mark it as an exhibit. The book is treated as if marked Ct. Ex. 1.

On August 22, 2017, ORI filed a motion to complete the record, requesting to substitute a complete copy of ORI Ex. 66⁴ which was admitted at hearing. On August 24, 2017, Respondent objected to the substitution and moved to strike ORI Ex. 66 admitted at hearing. Respondent’s objection is overruled and the motion to strike is denied. Respondent’s objection raises significant questions regarding the weight I should accord ORI Ex. 66, – both the version admitted at hearing and the substituted version. However, Respondent has not stated adequate grounds to prevent the substitution or to warrant striking ORI Ex. 66. The ORI motion to complete the record is granted. The version of ORI Ex. 66 ORI offers as a substitute is treated as if marked ORI Ex. 66. Both the original ORI Ex. 66 admitted at hearing and the substituted ORI Ex. 66 will be considered in determining the weight of the evidence contained in those documents considering Respondent’s challenges to those documents.

ORI filed its post-hearing brief (ORI Br.) on October 24, 2017, with appendices 1 through 9. Respondent filed his post-hearing brief (R. Br.) on October 24, 2017, with appendices 1 through 3. The parties filed post-hearing replies on December 27, 2017 (ORI Reply and R. Reply, respectively).

Respondent objects to the ORI post-hearing briefing on several grounds. R. Reply at 2-5. In the Prehearing Order ¶ III.E, I advised the parties that I would accept post-hearing briefs and post-hearing response briefs in accordance with 42 C.F.R. § 93.522. I directed that: post-hearing briefs include proposed Findings of Fact and Conclusions of Law;

⁴ Citations in this decision are to the Supplement to ORI Ex. 66 filed by ORI on August 22, 2017, DAB E-File # 51a.

prehearing pleadings could be incorporated by reference; the total length of each brief would not exceed 30 pages; copies of regulations or statutes not currently in effect could be attached to one of the briefs as an attachment. Prehearing Order ¶ III.E. I gave the parties additional instructions regarding post-hearing briefing at the end of the hearing. I advised the parties that they could file as an appendix to one of their post-hearing briefs: proposed Findings of Fact and Conclusions of Law; the list of errata to the transcript; and a list of their exhibits with status indicated. I again advised the parties that each brief could not exceed 30 pages. I suggested that counsel consider using a matrix to help summarize the evidence for my benefit. I advised counsel that addenda to the briefs do not count in the page limitations and proposed findings of fact and conclusions of law could be incorporated in the brief by reference. Tr. 833-49. On October 23, 2017, Respondent requested leave to use 36 pages for his opening post-hearing brief and offered to limit his post-hearing reply to 24 pages. DAB E-File Item # 57. On November 2, 2017, ORI opposed Respondent's motion. DAB E-File Item # 61. No ruling was issued as Respondent's motion was rendered moot by the parties' filing their opening post-hearing briefs on October 24, 2017.

On October 24, 2017, ORI filed its post-hearing brief and nine appendices. The nine appendices are: (1) List of Admitted ORI Exhibits; (2) ORI Issue Matrix; (3) Proposed Findings of Fact and Conclusions of Law; (4) List of Errata in Hearing Transcript; (5) Index of Respondent's Inconsistencies, Misstatements, and Mischaracterizations; (6) Winter Brain 2009; (7) Society for Neuroscience 2008; (8) Department of Veterans Affairs Handbook 0700; and (9) Clazosentan and BQ-123 Chemical Structures. Respondent filed on October 24, 2017, his post-hearing brief and three appendices: (1) a list of Respondent's admitted exhibits; (2) a table of ORI issues; and (3) a table of culpability. Respondent objected to my consideration of ORI Appendices 6, 7, and 9 as substantive evidence because they are offered in violation of 42 C.F.R. § 93.513. R. Reply at 3-5. ORI did not offer as substantive evidence on the merits prior to the hearing or as rebuttal during the hearing the documents appended to its post-hearing brief as Appendices 6, 7, and 9. Those documents appear to be filed with the intent to rebut or attack the credibility of Respondent's testimony. The Prehearing Order ¶ III.B and 42 C.F.R. §§ 93.513, 93.517(e), and 93.519(k) contemplate that documentary evidence on the merits will be exchanged and offered in advance of hearing and that rebuttal evidence will be offered at hearing. There is no provision in either the Prehearing Order or the regulations for the submission of substantive evidence after a hearing is completed. ORI did not mark Appendices 6, 7, and 9 as exhibits. ORI did not move to reopen the hearing for the taking of additional evidence. Respondent's objection is sustained and Appendices 6, 7, and 9 offered by ORI are not accepted as evidence and not considered as such. Respondent also objects to ORI Appendix 5 on grounds that it is an attempt to avoid the 30-page limit I placed on opening briefs. Appendix 5 to the ORI post-hearing brief is titled "Index of Respondent's Inconsistencies, Misstatements, and Mischaracterizations." I specifically advised counsel at the conclusion of the hearing that I find a matrix summarizing the evidence helpful. Tr. 847. I did not require the parties to

summarize the evidence in a matrix in their post-hearing briefs but left to their discretion whether to place one in their brief or attach one as an appendix or addendum, which I stated would not count in the page limitation of the briefs. Tr. 843. Respondent also used an appendix to summarize the evidence. I conclude that ORI did not abuse the discretion I granted the parties to provide a matrix summarizing the evidence as a tool to assist me in deciding this case. Respondent's objection to Appendix 5 to the ORI post-hearing brief is overruled.

II. Discussion

A. Issues

Whether ORI has shown by a preponderance of the evidence that Respondent committed research misconduct by intentionally, knowingly, or recklessly engaging in "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results," and such conduct was a "significant departure from accepted practices of the relevant research community." 42 C.F.R. §§ 93.103, 93.104, 93.516, 93.517(a); Joint Statement of Issues Presented for Hearing.

Whether ORI has shown by a preponderance of the evidence that proposed administrative actions are reasonable under the circumstances. 42 C.F.R. § 93.516(b)(3).

Whether Respondent established by a preponderance of the evidence any honest error, difference of opinion, affirmative defenses, or mitigating circumstances. 42 C.F.R. § 93.516(b)(2)-(3).

In my April 29, 2016 "Ruling Accepting Request for Hearing; Order for Further Case Development; and Notice of Final Prehearing Conference and Hearing Dates," ¶ I.C., I ruled that in his request for hearing, "Respondent preserved no issue as to the reasonableness of the administrative actions proposed by ORI if scientific misconduct is established." In its Memorandum of Points and Authorities In Support of The Government's Motion for Summary Judgment, filed August 22, 2016, at 8 n.4, ORI stated that, despite my having found that Respondent waived the issue, ORI continued to believe it must make a prima facie showing of the reasonableness of the proposed administrative remedies. During the final prehearing conference on June 23, 2017, ORI and Respondent agreed that the issue of the reasonableness of the administrative actions had not been waived and remained in issue. Although I previously concluded that Respondent waived the issue, ORI persists, and I therefore consider the issue of the reasonableness of the proposed administrative remedies in this decision.

B. Applicable Law

1. Congressional Authorization for Research Funding and Requirement for Investigation of and Imposition of Remedies for Research Misconduct

Congress directed the Secretary (the Secretary) of the U.S. Department of Health and Human Services (HHS) to use the PHS⁵ to encourage, cooperate with, and assist other public authorities, scientific institutions, and scientists to conduct research, investigations, experiments, demonstrations, and studies related to the causes, diagnosis, treatment, control, and prevention of human diseases and impairments. Congress authorized the Secretary to make grants-in-aid of such projects and to take other actions specified. 42 U.S.C. § 241. Congress also directed that the Secretary establish the ORI and appoint a director experienced and specially trained in conducting research with experience in investigating research misconduct. Congress directed that the Secretary promulgate regulations that: define the term “research misconduct”; establish a process for entities that receive financial assistance from HHS to investigate and report research misconduct to the ORI; require entities that receive financial assistance to agree to comply with the regulations issued by the Secretary; establish a process for ORI to receive, investigate, and to take appropriate actions, including imposing remedies, when research misconduct is found; and provide for the protection of whistleblowers. 42 U.S.C. § 289b.

2. The Secretary and Institutions and Individuals Who Apply For or Receive PHS Support Are Responsible for the Integrity of the Research Process and Preventing and Reporting Research Misconduct

The Secretary’s regulations regarding research misconduct are currently found in 42 C.F.R. pt. 93 entitled “Public Health Service Policies on Research Misconduct.”⁶ The general policy stated by the regulations is that the Secretary and institutions that apply for or receive funds from PHS for biomedical or behavioral research, research training or related activities share responsibility for the integrity of the research process. HHS has the ultimate oversight authority for PHS-supported work. Institutions and members of institutions receiving PHS funds have an affirmative duty to protect PHS funds from

⁵ In this case the grants subject to my jurisdiction were all administered by the National Institutes of Health (NIH) an agency of PHS.

⁶ The current regulations were effective on June 16, 2005, at which time the prior regulations at 42 C.F.R. pt. 50 were removed. 70 Fed. Reg. 28,370, 28,384 (May 17, 2005).

misuse by ensuring the integrity of all PHS-funded work, including the responsibility to respond to and report research misconduct. 42 C.F.R. § 93.100(b).

The regulations apply to every institution that applies for or receives PHS support for biomedical or behavioral research, research training, or activities related to the PHS supported research or research training. 42 C.F.R. § 93.102. The term institution is defined by the regulations to include any of the following who “apply for or receives PHS support for any activity or program that involves the conduct of biomedical or behavioral research, biomedical or behavioral research training, or activities related to research or training:” individuals and persons, colleges and universities, PHS intramural biomedical or behavioral research laboratories, research and development centers, national user facilities, industrial laboratories or other research institutions, small research institutions, and independent researchers. 42 C.F.R. § 93.213. An institutional member is a person who is an employee, an agent, or affiliated by contract or agreement with an institution, including officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, student, volunteers, agents, and contractors, subcontractors, and sub-awardees and their employees. 42 C.F.R. § 93.214. Thus, virtually anyone connected to research or research training supported by PHS or for which PHS support was requested, is subject to the prohibition against research misconduct and subject to administrative actions in the event they commit research misconduct.

3. Research Misconduct Defined

Research misconduct is defined as “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.” 42 C.F.R. § 93.103. Fabrication is “making up data or results and recording or reporting them.” 42 C.F.R. § 93.103(a). 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.” 42 C.F.R. § 93.103(b). Plagiarism is defined as “appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.” 42 C.F.R. § 93.103(c). The regulation is clear that fabrication, falsification, or plagiarism must occur in the context of proposing research for PHS funding, performing PHS funded research and, possibly, for performing research for which PHS funding was requested but denied, reviewing PHS funded research, or reporting PHS funded research results. Fabrications, falsifications, or plagiarism in grant applications not submitted to PHS, in conducting or reviewing research for which no PHS funding was requested, or in draft reports, articles, posters and the like that were prepared but not reported, i.e. not released, published, or otherwise disseminated, are all arguably not research misconduct under the regulatory definitions.

4. Proving Research Misconduct

(a) Definitions of Knowing, Intentional, and Reckless

The institution investigating an allegation of research misconduct or ORI bears the burden of proving an allegation of research misconduct by a preponderance of the evidence. 42 C.F.R. §§ 93.106(b)(1), 93.516(b)(1). There are four elements or requirements, each of which must be established by the preponderance of the evidence, in order to prove that research misconduct occurred: (1) there must be fabricated, false, or plagiarized material; (2) the fabricated, false, or plagiarized material must have been used in proposing, performing, reviewing, or reporting PHS funded research; (3) the conduct must be a significant departure from accepted practices in the relevant research community; and (4) the misconduct must have been committed intentionally, knowingly, or recklessly. 42 C.F.R. § 93.104. Failure to show any one of the four elements by a preponderance of the evidence, that is, the existence of the element is shown by admissible, competent, and weighty evidence, to be more likely true than not, requires the conclusion that research misconduct has not been proven. 42 C.F.R. § 93.219. The respondent, i.e., the individual or entity accused of research misconduct, has the burden to establish by a preponderance of the evidence any affirmative defenses, including honest error or difference of opinion, and any mitigating factors relevant to HHS administrative actions based on a finding of research misconduct. 42 C.F.R. §§ 93.106(b)(2) and (3), 93.516(b)(2) and (3). A preponderance of the evidence is a quantum of evidence that when compared to opposing evidence, leads to the conclusion that a fact in issue is more probably true than not. 42 C.F.R. § 93.219.

Honest error and differences of opinion are specifically excluded from the definition of research misconduct. 42 C.F.R. § 93.103(d). Pursuant to 42 C.F.R. §§ 93.106(b)(2) and 93.516(b)(2), Respondent has the burden of proving by a preponderance of the evidence any affirmative defenses, including honest error or difference of opinion. The drafters of 42 C.F.R. § 93.106(b)(2) and 93.516(b) clearly state that honest error or difference of opinion are affirmative defenses. However, the drafters, citing *Martin v. Ohio*, 480 U.S. 228 (1987), also provide that credible admissible evidence that respondent submits to prove honest error or difference of opinion must be considered when deciding whether or not ORI or the institution meets its burden of proving by a preponderance of the evidence that research misconduct was committed intentionally, knowingly, or recklessly. 70 Fed. Reg. at 28,372; *Id.* at 28,378. In *Martin*, the Supreme Court found no violation of the Due Process Clause of the Fourteenth Amendment where the defendant's evidence of self-defense was considered for purposes of negating the state's prima facie showing beyond a reasonable doubt of aggravated murder; but where the jury was also instructed that the defendant must show the affirmative defense of self-defense by a preponderance of the evidence rather than requiring the state to prove absence of self-defense as an element of its prima facie case, where the absence of self-defense was not an element of aggravated murder under state law. Therefore, in a research misconduct case, the drafters

of the regulation have made clear that respondent's evidence of honest error or difference of opinion must be considered for whether it negated the ORI or institution's prima facie showing of intentional, knowing, or reckless research misconduct and whether respondent established honest error or difference of opinion as an affirmative defense. ORI does not bear the burden to prove as part of its prima facie showing the absence of honest error or difference of opinion. The drafters state:

It is important to note that possible honest error or difference of opinion goes to the issue of whether the alleged research misconduct was committed intentionally, knowingly, or recklessly, not whether the allegation involves fabrication, falsification, or plagiarism. A finding that the research misconduct is conducted intentionally, knowingly, or reckless [sic] is necessary for a finding of research misconduct; a finding that is not made until the investigation is completed, absent an admission at an earlier stage.

70 Fed. Reg. at 28,378.

There are no definitions established by 42 C.F.R. pt. 93 or any discussion in the final rulemaking regarding the definitions of the terms intentionally, knowingly, or recklessly as used in 42 C.F.R. § 93.104(b). The parties were invited to provide appropriate authority to establish how these terms, which establish a scienter requirement to be proved by ORI, should be interpreted and applied in this case. The parties were also invited to discuss the term "relevant research community" which is also undefined in the ORI regulations, specifically, how it should be interpreted and applied.⁷ Ruling Accepting Request for Hearing; Order for Further Case Development; and Notice of Final Prehearing Conference and Hearing Dates issued April 29, 2016 ¶ I.C (DAB E-File Item # 9).

ORI argues that the three terms, intentionally, knowingly, and recklessly, were intended to have different meanings by the drafters of 42 C.F.R. pt. 93. Although the drafters apparently did not perceive the need to provide definitions of those terms for those required to enforce the regulations, I accept as self-evident that the drafters intended the terms to have different meanings. ORI relies upon prior decisions of appellate panels and ALJs of the Departmental Appeals Board under the prior ORI regulations for definitions.

⁷ Given the amount of detail in the regulations, it is inexplicable that the drafters failed to provide definitions for these key terms and elements of the ORI prima facie case.

ORI proposes that “intentionally” means that a researcher engages in falsification, fabrication, or plagiarism with the intent, or purpose, of misleading the reader of the researcher’s research record, citing *Dr. Rameshwar K. Sharma*, DAB No. 1431 (1993). The problem with this definition is that it requires ORI to show by a preponderance of the evidence that, not only did the respondent in a research misconduct proceeding have the general intent to use false, fabricated, or plagiarized material, but ORI must also show that the researcher had the specific intent to affect the reader or end-user. The heightened showing by ORI of a specific intent to mislead does not appear to be required by the regulatory language or the underlying statute. Rather, the regulation seems to permit a finding of research misconduct if the respondent in a research misconduct proceeding simply intended to use false, fraudulent, or plagiarized materials.⁸

ORI argues that knowingly should mean that a researcher has actual knowledge that materials used are false, fabricated, or plagiarized and acts in deliberate ignorance or plain indifference to the falsity, fabrication, or plagiarism, citing *Scott J. Brodie*, DAB CR2056 (2010), *aff’d*, *Brodie v. U.S. Dep’t of Health & Human Servs.*, 796 F. Supp. 2d 145 (D.D.C. 2011). The term “plain indifference” is not contained in the regulation and it is not discussed in the preamble to the regulations. Adding a plain indifference standard simply adds an additional term that must be defined. It is also not clear from the ORI discussion how a plain indifference standard differs from the recklessly standard specifically adopted in the regulations. I decline to adopt a “plain indifference” standard. The term “deliberate ignorance” is also problematic because it requires a heightened showing of a respondent’s mental state. I find no intent on the part of the drafters to impose such a heightened burden on ORI.

ORI argues that recklessly should mean that the respondent either knew or should have known that there is an increased risk that materials are false, fabricated, or plagiarized but the researcher uses the material anyway, citing the district court opinion in *Brodie*, 796 F.

⁸ The distinction between general and specific intent is generally discussed in the context of criminal offenses. Simply stated, a general intent crime simply prohibits a specific voluntary act, but a specific intent crime requires the intent to cause a particular result or to achieve a specific purpose. Specific intent requires that the defendant intend to act and cause a specific result or to accomplish a specific purpose. General intent only requires that the defendant intended to act. 22 C.J.S. *Criminal Law: Substantive Principles* § 36 (2018). The drafters’ citation to *Martin* clearly shows they were considering criminal precedent in crafting the regulations and I am not persuaded they intended to burden ORI with the requirement to show specific intent absent a clear statement of the intent to do so.

Supp. 2d 145, 153. ORI states that simple neglect is an insufficient basis for finding research misconduct. ORI Memorandum of Points and Authorities in Support of the Government's Motion for Summary Judgment at 20-23 (DAB E-File Item # 11b). The drafters' use of the term recklessly certainly indicates that they contemplated that more than ordinary or inadvertent negligence⁹ is necessary to constitute research misconduct.

Respondent argues that absent a definition for terms in a regulation, words should be given their common meaning. Petitioner argues, citing the Model Penal Code, that a knowing and intentional standard requires a higher degree of culpability than the lesser standard of recklessness. Intentionally or intentional, according to Respondent, requires that an act is "[d]one with the aim of carrying out the act," citing *Black's Law Dictionary* 814 (4th ed. 1999). R. Br. at 13. Respondent pushes the definition further, arguing that the definition supports a conclusion that in order to intentionally commit research misconduct, a researcher must "falsify, fabricate, or plagiarize research with the specific intent of misleading." R. Br. at 13-14. Respondent does not explain how the *Black's Law Dictionary* definition of intentional is stretched from the general intent to commit the act to include the specific intent to mislead. Respondent cites *Sharma*, DAB No. 1431, to support his position that specific intent to mislead or deceive is required. Respondent then goes on to concede that ORI is "not required to prove motive as a component of misconduct." R. Br. at 14. Respondent asserts, however, that the absence of any motive to deceive is relevant to assessing intent, as the Board commented in *In re Thereza Imanishi-Kari, Ph.D.*, DAB No. 1582 (1996). It is not clear from the Board's decision in *Imanishi-Kari* exactly what it meant by the comment. The Board, which found against ORI, was deciding the case under a much different regulatory scheme that, according to the decision, required that ORI show deliberate and intentional fabrication or falsification. Respondent does not explain how, under the current regulatory scheme, under which ORI is only required to prove that Respondent intended to act, a showing by Respondent of no intent to deceive is relevant to assessing intent, except with regard to aggravating and mitigating factors related to ORI's proposed administrative actions. Respondent cites three Federal Circuit Court of Appeals decisions involving personnel actions based in part on the submission of false information to the employing agency. In those cases, the court relied upon prior decisions that concluded that the agencies involved were required to show both that the employee provided false information and that he or she did so with the specific intent to deceive, mislead, or defraud the agency. R. Br. at 14-15. The cases cited by Respondent do not appear to have involved a

⁹ Inadvertent or simple negligence means that the actor is not aware of the unreasonable risk associated with the act but should have foreseen and avoided the risk. Ordinary negligence means that the actor failed to use ordinary diligence or care. *Black's Law Dictionary* 1063 (8th ed. 2004) (citations are to the 8th ed. 2004, unless otherwise indicated).

regulatory scheme such as that established by the Secretary and applicable in this case, which requires that ORI prove a general intent to act but not a specific intent to defraud, mislead, deceive, or cause other effect upon the recipient or reader.

Respondent argues, citing various authorities, that “to knowingly do an act, the actor must have actual knowledge of what he is doing and must proceed forward deliberately, and the act cannot be done by mistake or accident.” R. Br. at 18.

Regarding recklessly, Respondent distills from various authorities the definition that one acts recklessly in the context of research misconduct when one acts or fails to act, knowing that there was a substantially or unjustifiably high risk that research used was false, fabricated, or plagiarized, and despite knowledge of the risk, used the research anyway. Respondent asserts that the definition of reckless includes knowledge of potential for harm. R. Br. at 18-19.

Generally, the courts give substantial deference to an agency interpretation of its own regulation so long as the interpretation is consistent with the regulation and the agency’s prior construction of the regulation. The same rules for interpreting statutes apply to interpreting regulations. The plain meaning rule is a basic rule of interpretation that requires, to the extent possible, the meaning of a regulation should be gleaned from the words used. Another basic rule is the common meaning rule which requires that when a regulatory term is not given a specific regulatory definition, the commonly understood meaning of the term is to be used. Because terms used in various regulations promulgated by an agency may not be consistently used, the entire regulation should be considered in attempting to discern a meaning of a specific term within the regulation prior to looking to some other interpretive tool. Agency statements in final rulemaking about the purpose, goals, or intent of the regulations may be considered in determining what the agency intended.¹⁰ Regulatory history beyond what is stated in rulemaking may also be considered. The canons of statutory construction may also be used. 3 Charles H. Koch, Jr. & Richard Murphy, *Admin. L. & Prac.* § 10:26 (3d ed. 2018). The ORI regulations provide that any interpretation of 42 C.F.R. pt. 93 “must further the policy and purpose of the HHS and the Federal government to protect the health and safety of

¹⁰ Each agency submitting a proposed or final rule for publication in the Federal Register must provide a preamble to inform the reader of the basis and purpose of the regulation or proposal. 1 C.F.R. § 18.12. In promulgating regulations, the Secretary must publish the proposed regulation in the Federal Register and allow no fewer than 60 days for public comment. Social Security Act § 1871 (42 U.S.C. § 1395hh).

the public, to promote the integrity of research, and to conserve public funds.” 42 C.F.R. § 93.107.

According to the *Merriam-Webster Dictionary*,¹¹ intention means “a determination to act in a certain way.” Knowing means “having or reflecting knowledge, information, or intelligence.” Merriam-Webster.com (last updated May 18, 2018). Reckless means “marked by lack of proper caution” or “careless of consequences.” Merriam-Webster.com (last updated May 10, 2018). According to *Black’s Law Dictionary*, intentional means “[d]one with the aim of carrying out the act.” *Black’s Law Dictionary* 826. The first listed definition of knowing is “[h]aving or showing awareness or understanding; well informed.” The second listed definition of knowing is “[d]eliberate; conscious.” *Id.* 888. *Black’s* defines reckless as “[c]haracterized by the creation of a substantial and unjustifiable risk of harm to others and by a conscious (and sometimes deliberate) disregard for or indifference to that risk; heedless; rash.” *Id.* 1298. *Black’s* definition comments that reckless conduct is much more than mere negligence: it is a gross deviation from what a reasonable person would do. I accept *Merriam-Webster*, a lay-person’s standard resource, and *Black’s Law Dictionary*, the attorney’s standard resource, as providing the common definitions for intentional, knowing, and reckless and their adverb forms. I conclude that intentionally means one acts with the aim of carrying out the act. Knowingly means that one acts with knowledge and information and awareness of the act. Recklessly means one acts without proper caution despite a known risk for harm. In the context of research misconduct, I conclude that ORI must show by a preponderance of the evidence, that Respondent:

- Intended to use false, fabricated, or plagiarized materials, whether or not he or she accomplished the use of such materials; or
- Used false, fabricated, or plagiarized materials knowing that they were false, fabricated, or plagiarized; or
- Used materials without exercising proper care or caution and disregarding or showing indifference to the risk that the materials were false, fabricated or plagiarized thereby causing harm to the integrity of the research process or waste of public funds, the basis for regulating research misconduct stated in 42 C.F.R. § 93.100.

¹¹ Merriam-Webster.com (last updated May 27, 2018).

(b) Definition of the Relevant Research Community and Accepted Practices

ORI is also required to show by a preponderance of the evidence that Respondent's conduct is a "significant departure from accepted practices of the relevant research community." 42 C.F.R. § 93.104(a). This concept is also not defined further in the ORI regulations or the rulemaking. However, considering the plain language of the regulation, ORI is required to establish what the "relevant research community" is. The regulations provide no different statement as to the quantum of evidence required for this showing and, therefore, I conclude ORI must make this showing by a preponderance of the evidence. ORI is also required to establish by a preponderance of the evidence the "accepted practices" of the relevant research community. And ORI needs to show that Respondent's conduct is a significant departure from accepted practices within that community. ORI asserts that Respondent's conduct was a significant departure from accepted practices in the relevant research community. Memorandum of Points and Authorities In Support of The Government's Motion for Summary Judgment, filed August 22, 2016, at 17-20; ORI. Br. at 10-12; ORI Reply at 24-25. However, ORI never specifically explains how an ALJ should identify the relevant research community; what are accepted practices in that community; or what constitutes a significant departure. The ORI arguments and the evidence ORI cites – ORI Exs. 71 through 74¹² – suggest that ORI takes the position that the relevant research community is the entire community of institutions and researchers who apply for and/or receive PHS grants (PHS grants community). ORI gives no indication that it takes a position that the relevant research community might be limited to particular types of grants, particular types of research, or particular geographic regions or areas, types of institutions, or other smaller communities than the entirety of those receiving grants or applying for grants. ORI also suggests that

¹² ORI Exs. 71 and 72 are an article and an editorial. The documents express the views of the authors that certain conduct or researchers is or should be considered misconduct or unethical. However, ORI has presented no evidence that either the publications or their authors are acceptable and authoritative sources for accepted practices in any research community. ORI Exs. 73 and 74 are simply retraction notices that reflect on their face that they are based on the WSU Investigation of Respondent but express no opinion regarding accepted practices in the research community. ORI Ex. 74 states that the retraction was at the behest of WSU. ORI Ex. 74 also states that "[t]he retracted article will remain online to maintain the scholarly record, but it will be digitally watermarked on each page as 'Retracted.'" ORI Ex. 74 at 2. ORI Ex. 74 may be argued to show it is acceptable in the research community to keep retracted materials of questionable integrity available to the research community.

conduct that violates the regulations is not accepted in the PHS grants community. I hasten to note, however, that for a finding of research misconduct, the regulations are clear that the conduct must be a significant departure from accepted practices of the relevant research community. Defining the community is therefore critical to the ORI case.

Respondent does not offer any definition for the phrase “departure from accepted practices of the relevant research community.” Respondent does suggest that the relevant research community should be WSU where Respondent was employed. Respondent argues that he acted within the accepted practices of the WSU community. R. Br. at 11-12; R. Reply at 13-15.

Although the statutes and regulations do not specify what accepted practices of the relevant research community are, it is possible to identify several possible research communities that may be pertinent.¹³ For example, they could be: the community of researchers and research institutions around the world; all researchers and research institutions in the United States; university-based researchers and institutions; corporate or industry-based research institutions; researchers involved in specific types of research; and so forth. In this case, we can readily narrow the relevant community to that to which 42 C.F.R. pt. 93 applies, which is certainly a relevant research community. Congress directed the Secretary to use the PHS to encourage, cooperate with, and assist other public authorities, scientific institutions, and scientists to conduct research, investigations, experiments, demonstrations, and studies related to the causes, diagnosis, treatment, control, and prevention of human diseases and impairments. Congress also authorized the Secretary to make grants-in-aid of such projects. 42 U.S.C. § 241. Congress directed that the Secretary establish the ORI and appoint a director experienced and specially trained in conducting research with experience in investigating research misconduct. Congress directed that the Secretary promulgate regulations that: define the term “research misconduct”; establish a process for entities that receive financial assistance from HHS to investigate and report research misconduct to the ORI; require entities that receive financial assistance to agree to comply with the regulations issued by the Secretary; establish a process for ORI to receive, investigate, and to take appropriate actions, including imposing remedies, when research misconduct is found; and provide for the protection of whistleblowers. 42 U.S.C. § 289b. By its mandates Congress established and identified a relevant research community and directed the Secretary to establish by regulation accepted practices related to PHS grants. The Secretary has acted

¹³ It is also inexplicable that the drafters of the ORI regulations did not establish a more clear definition of the research community and a standard for accepted practices. Regulated entities should be given clear notice of the standards to which they are bound to comply or face sanction.

in accordance with the direction of Congress and established 42 C.F.R. pt. 93 for the regulation of the relevant scientific community that applies for grants for authorized purposes from PHS.

The general rules established by 42 C.F.R. pt. 93 require that the Secretary and institutions that apply for or receive funds from PHS for biomedical or behavioral research, research training, or related activities share responsibility for the integrity of the research process. Institutions and members of institutions receiving PHS funds have an affirmative duty to protect PHS funds from misuse by ensuring the integrity of all PHS-funded work, including the responsibility to respond to and report research misconduct. 42 C.F.R. § 93.100(b). Thus, the overarching definition of accepted practices requires that they are consistent with ensuring the integrity of all PHS-funded work. The regulations apply to every institution that applies for or receives PHS support for biomedical or behavioral research, research training, or activities related to the PHS-supported research or research training. 42 C.F.R. § 93.102. Institutions include individuals and persons who receive PHS research support, including colleges and universities, PHS intramural biomedical or behavioral research laboratories, research and development centers, national user facilities, industrial laboratories or other research institutes, small research institutions, and independent researchers. 42 C.F.R. § 93.213. Thus, the overarching relevant research community is the community of researchers and institutions that apply for and receive PHS grants. Accepted practices in the relevant research community are those established by 42 C.F.R. pt. 93. Whether or not there are other relevant accepted practices of relevant research communities that are subsets of the research community that apply for or receive PHS grants is largely a question of fact. Whether or not conduct is a significant departure from accepted practices in the relevant research community is also a question of fact. Whether or not ORI meets its burden of persuasion to establish as fact that Respondent's conduct was a significant departure from accepted practices of the relevant research community is discussed in the "Analysis" section hereafter. Whether or not Respondent rebuts the ORI prima facie showing with evidence of another relevant research community with accepted practices that differ from practices acceptable under the regulations is also a question of fact that is resolved as discussed in the "Analysis" section that follows.

5. Due Process Requirements

Subject to three specific exceptions not applicable in this case, action by ORI based on research misconduct is limited to such misconduct that occurred during the six years preceding the date HHS or the institution received the allegation of research misconduct. 42 C.F.R. § 93.105. As discussed hereafter, I find that WSU received the complaint of research misconduct against Respondent on about February 10, 2011. ORI Ex. 1 at 6. Therefore, any allegations of research misconduct prior to February 11, 2005, are time-barred in this case. 42 C.F.R. § 93.105(a).

Institutions are required to establish policies and procedures to address allegations of research misconduct. Institutions are responsible to assure the Secretary and the PHS that they have the required policies and procedures and that they are in compliance with 42 C.F.R. pt. 93. Institutions are responsible for securing research records and evidence; for establishing policies and procedures for the investigation of allegations of research misconduct; for conducting an inquiry based on an allegation of research misconduct to determine if an investigation is necessary; for conducting an investigation when determined necessary; for reporting to ORI when initiating and completing an investigation. 42 C.F.R. § 93.300-.318.

ORI is granted the authority to, *inter alia*, review institutional investigations, request additional information, make a finding of research misconduct, propose remedial administrative actions to the Secretary as authorized by 42 C.F.R. § 93.407, and propose debarment or suspension to the debarring official. 42 C.F.R. § 93.400, .403-.404.

If ORI makes a finding of research misconduct or seeks to impose HHS administrative actions, it must notify the respondent by a charge letter. If suspension or debarment is also proposed, the HHS debarring official issues a notice of proposed debarment or suspension to the respondent as part of the charge letter. The charge letter must include the ORI findings of research misconduct; the basis for the findings; any proposed administrative actions; and advise the respondent of the right to contest the findings and proposed administrative actions. 42 C.F.R. § 93.405. The respondent has 30 days to contest the findings of research misconduct and proposed administrative actions. 42 C.F.R. §§ 93.406, 93.501(a).

The procedures for challenging ORI findings of research misconduct and proposed administrative actions are established by 42 C.F.R. pt. 93, subpt. E. A respondent has a right to contest ORI research misconduct findings and proposed administrative actions before an ALJ of the Departmental Appeals Board. The ALJ issues a recommended decision to the Assistant Secretary for Health who makes the final decision regarding administrative actions except debarment or suspension. If debarment or suspension is recommended, the Assistant Secretary's decision is treated as findings of fact for the HHS debarring official who makes the final determination for or against debarment or suspension. 42 C.F.R. § 93.500. The regulations establish parties' rights, which include the right to representation by an attorney, discovery, to participate in hearings, to present and cross-examine witnesses, and submit written briefs post-hearing. 42 C.F.R. §§ 93.505, 93.512, 93.513, 93.517. The regulations provide for an in-person hearing. The ALJ conducts a de novo review of the ORI findings of research misconduct and proposed HHS administrative actions. The ALJ is prohibited from reviewing the institution's procedures or misconduct findings or ORI's misconduct proceedings. 42 C.F.R. § 93.517(a)-(b).

C. Findings of Fact, Conclusions of Law, and Analysis

The parties stipulated to a number of facts in their “Joint Stipulation of Undisputed Facts” filed June 22, 2017 (Jt. Stip.). Their stipulations, that is, those facts upon which they agree, provide some context for the lengthy discussion that follows. The parties stipulated that:

Traumatic brain injury (“TBI”) is one of the foremost causes of disability and death suffered by U.S. soldiers in Iraq and Afghanistan and by children and young adults in the residential population. Among several major pathological events, TBI also results in a series of vascular functional etiologies including: (1) cerebral edema, which results in increased intracranial pressure; (2) diffuse axonal injury, which disrupts the neural circuitry underlying cognition and motor control; and (3) chronic hypoperfusion of the brain parenchyma and microglial activation, which leads to alterations in brain microcirculation. While clinical studies have focused on strategies to reduce the extent of cerebral edema and diffuse axonal injury, effective treatments for hypoperfusion following TBI remains elusive.

Jt. Stip. ¶ 1 (footnotes omitted). Although not specifically stipulated, I infer that Respondent’s research was related to the foregoing stipulation.

The parties stipulated that WSU is the institution by which Respondent was employed. On December 1, 2011, the Associate Vice President for Research and WSU Deciding Official accepted the conclusions of the WSU Investigation that Respondent committed research misconduct. By letter dated February 29, 2012, Respondent was advised that the findings of the investigating committee were upheld and administrative actions were imposed, including immediate termination of Respondent, reassignment of Respondent’s grants, requests by WSU to retract five publications, and notification of ORI of the actions. Jt. Stip. ¶¶ 2-3; ORI Ex.20.

There are some additional facts not stipulated by the parties, but not in dispute.

Respondent worked for Jose Rafols, Ph.D. as a Research Assistant from November 22, 2004 until November 14, 2008. Respondent was appointed Assistant Professor (Research) at WSU on November 15, 2008. Respondent was appointed to a tenure-track position as Assistant Professor in the Department of Anatomy and Cell Biology at WSU on November 30, 2009. ORI Ex. 1 at 36.

The complaint of research misconduct was made against Respondent on or about February 10, 2011, and an inquiry committee was convened that determined on March 10, 2011 that further investigation was warranted. ORI Ex. 1 at 6, ORI Ex. 21. The complainant was Christian A. Reynolds, a former graduate student who worked in Respondent's laboratory. ORI Ex. 1 at 6, 36. According to the WSU Investigation report the complaint was that Respondent misrepresented figures and data published in the journal *Neurological Research*. But the WSU Investigation found several additional instances of misrepresentations. ORI Ex. 1 at 36. On about November 30, 2011, the WSU Investigation, which was composed of four WSU faculty, issued its final report finding that Respondent engaged in research misconduct. ORI Ex. 1 at 3-43.

The parties stipulated that, based on ORI's review of the report of the WSU Investigation, ORI issued a charge letter on February 10, 2016 (four years after the WSU Investigation report was issued) charging that "Respondent intentionally, knowingly, or recklessly reused and falsely labeled sixty-four images and graphs that were included in six unfunded NIH grant applications, one funded NIH grant, three publications, five posters, and one book over a period of five years." Jt. Stip. ¶ 4. ORI proposed in the charge letter a ten-year debarment, a ten-year ban on serving as an advisor to PHS, and an ORI notice to journals to retract affected articles published. Jt. Stip. ¶ 5.

My conclusions of law are set forth in bold text followed by my findings of fact and analysis. I have carefully considered all the evidence and the arguments of both parties, though not all may be specifically discussed in this decision. I discuss in this decision the credible evidence given the greatest weight in my decision-making.¹⁴ I also discuss any evidence that I find is not credible or worthy of weight. The fact that evidence is not specifically discussed should not be considered sufficient to rebut the presumption that I considered all the evidence and assigned such weight and probative value to the credible evidence that I determined appropriate within my discretion as an ALJ. There is no requirement for me to discuss the weight given every piece of evidence considered in this case, nor would it be consistent with notions of judicial economy to do so. Charles H. Koch, Jr., *Admin. L. and Prac.* § 5:64 (3d ed. 2013).

1. Respondent has the right to a hearing before an ALJ and I have jurisdiction to render a recommended decision.

The ORI Charges allege research misconduct related to grant applications for PHS funding for research or the reporting of PHS-funded research. Jt. Stip. ¶ 4; ORI Ex. 69

¹⁴ "Credible evidence" is evidence that is worthy of belief. *Black's Law Dictionary* 596. The "weight of evidence" is the persuasiveness of some evidence compared to other evidence. *Id.* at 1625.

¶¶ 4-5. Accordingly, 42 C.F.R. pt. 93 applies and I have jurisdiction in this case. 42 C.F.R. § 93.102(b). Respondent has the right to contest before an ALJ the ORI allegations of research misconduct and proposed administrative actions, including debarment or suspension. 42 C.F.R. § 93.500(b).

2. The following conclusions of law apply to all research misconduct charges and affect determinations as to the credibility, probative value, and weight of the evidence.

Before turning to the specific charges against Respondent, it is helpful to address some issues that are pervasive in this case. In short, Respondent's position is that these issues taint the research misconduct proceedings; prevent ORI from making a prima facie case of research misconduct against him; and adversely reflect upon the reasonableness of the administrative actions¹⁵ ORI proposes. It is important to be mindful of the fact that research misconduct proceedings are not criminal proceedings and have none of the penalties associated with criminal convictions. 42 C.F.R. § 93.407 (authorized administrative actions). Further, while ORI is required to make a prima facie showing of research misconduct, ORI must show research misconduct by a preponderance of the evidence (more likely than not) and not beyond a reasonable doubt. 42 C.F.R. § 93.516. The difference between the preponderance of the evidence standard and the beyond a reasonable doubt standard is significant. In this case, Respondent takes a shotgun approach, blasting out as many pellets or issues as possible in an effort to damage the ORI prima facie case. The following examples apply generally to the entire case and not just individual allegations of research misconduct. It may be less confusing to examine these issues upfront rather than in the context of the individual allegations of research misconduct. But it is necessary to remember that each of these issues affects all allegations of research misconduct in this case.

¹⁵ ORI proposes and HHS is authorized to take "administrative action" against an individual or institution found to have engaged or that is engaging in research misconduct. The propose of such action is "to protect the health and safety of the public, to promote the integrity of PHS supported biomedical or behavioral research, research training, or activities related to that research or research training and to conserve public funds." 42 C.F.R. § 93.200(a). Authorized administrative actions are set forth in 42 C.F.R. § 93.407. Although the administrative actions authorized are clearly not punitive, they may in many instances have punitive effect when applied. The administrative actions are clearly remedial in effect as they are intended to stop research misconduct and restore integrity to the extent possible and preserve PHS funds. When referring in this decision to administrative actions or administrative remedies, I am referring to administrative actions defined in 42 C.F.R. § 93.200 and authorized by 42 C.F.R. § 93.407. I intentionally do not use the terms penalty or sanction to refer to the authorized HHS administrative actions.

a. The connection among WSU, ORI, and the Department of Veterans Affairs (VA) does not taint, bar, limit, or otherwise adversely affect the ORI charges of research misconduct, which are reviewed de novo in this proceeding.

Respondent correctly identifies that there exists an “interrelatedness” of the investigations conducted by WSU, the VA, and ORI. R. Br. at 27-28; R. Reply at 26-30. The fact that the investigations are all related is undeniable. Respondent, however, attempts to use the relatedness of the investigations to discredit the ORI findings and conclusions and the administrative actions. Respondent points to the March 10, 2017 decision of Dorothy L. Moran, Administrative Judge, sitting for the Merit Systems Protection Board (MSPB) in the case of *Christian Kreipke v. Dep’t of Veterans Affairs*, Docket Number CH-1221-15-0284-W-1. R. Ex. 21. Based on that decision Respondent asserts that “Judge Moran’s decision regarding the misconduct illustrates Respondent has been vindicated of any wrongdoing in any of the VA issues.” R. Reply at 26. Respondent’s carefully crafted statement is potentially misleading if not carefully read with knowledge of Judge Moran’s jurisdiction, the scope of her review, and her ultimate findings and conclusions which are discussed hereafter in a section specially dedicated to discussing the decision. I conclude after careful review of Judge Moran’s decision that it has little or no impact upon my decision, except perhaps to cause me to even more carefully scrutinize both the evidence and the parties’ pleadings. I certainly do not conclude, as Respondent suggests, that the ORI action is tainted, barred, limited, or otherwise affected by the interrelatedness of the investigations.

It is clear from the regulations that it is expected that in some cases there will be multiple agencies and/or institutions involved when allegations of research misconduct are made. Institutions such as WSU that receive PHS support for biomedical or behavioral research, related training, or activities related to research or training, share responsibility with HHS to ensure the integrity of the research process. Institutions like WSU that apply for and/or receive PHS grants and institutional members such as Respondent have an affirmative duty to protect PHS funds from misuse by ensuring the integrity of PHS-supported work. Further, institutions and their members have “primary responsibility for responding to and reporting allegations of research misconduct.” 42 C.F.R. § 93.100(b).

The regulations at 42 C.F.R. pt. 93, subpt. C establish the responsibilities of institutions for ensuring compliance in addressing research misconduct. Pursuant to 42 C.F.R. § 93.300, WSU was required, among other things, to respond to the allegations of research misconduct against Respondent; to cooperate with ORI; and to assist in administering any administrative actions HHS imposes. Pursuant to 42 C.F.R. §§ 93.307 through 93.309, WSU was required to determine whether the complaint that Respondent committed research misconduct required further inquiry and whether that inquiry triggered the need for an investigation. WSU’s investigation of Respondent was regulated by 42 C.F.R. §§ 93.310 through 93.318. WSU was required to keep ORI

informed throughout the process. 42 C.F.R. §§ 93.310(b), 93.311(c), 93.315, 93.316, 93.318.

Pursuant to 42 C.F.R. § 93.400(a)(5), ORI has authority to coordinate with other federal and state offices and agencies or institutions. The regulations specifically address coordination by ORI with other federal agencies when alleged research misconduct may be within the jurisdiction of more than one federal agency. In this case, both WSU, which is subject to ORI oversight and the VA, which is not subject to ORI oversight in the absence of any PHS funding, were potentially affected by allegations of research misconduct by Respondent. ORI Ex. 58 (VA investigation report). In this case, the evidence collected by the WSU Investigation was shared with the VA Office of Research Oversight (ORO) and is referred to in the VA investigation report. The VA investigation examined the exhibits from the WSU Investigation and materials provided by WSU through ORO. ORI Ex. 58 at 1-3. At the time of the alleged research misconduct, Respondent was a Health Science Specialist at the John D. Dingell VA Medical Center as well as being employed at WSU. ORI Ex. 58 at 3. The VA Investigation Committee found Respondent committed research misconduct in a report dated March 28, 2013. ORI Ex. 58. The WSU Investigation issued its findings of research misconduct in its report dated November 30, 2011. ORI Ex. 1.

Clearly there was a relationship between ORI and WSU. Alexander P. Runko, Ph.D. advised and assisted the WSU Investigation. ORI Ex. 1 at 1; Tr. 85-86. WSU shared evidence with the VA. I do not find that the relationship detracts from the credibility of the ORI findings and conclusions of research misconduct as reflected in the charge letter. ORI Ex. 67. In fact, the relationship was compelled by the regulations discussed above. Furthermore, I am not bound by the findings and conclusions of either the VA investigation (ORI Ex. 58) or the WSU Investigation (ORI Ex. 1). ORI uses evidence collected by, but does not rely upon, the findings and conclusions of either the WSU or VA investigations as the basis for the proposed administrative remedies. Rather, ORI relies upon the findings and conclusions of its own review of the evidence conducted by Runko, the former ORI Scientist-Investigator who conducted ORI's oversight of the WSU Investigation, advising and assisting with that investigation. ORI Ex. 69 at 1. Respondent complains that Runko's involvement with the WSU Investigation "skewed" the ORI findings and conclusions. R. Br. 27. Certainly, Runko's participation in the WSU Investigation raises a question as to whether or not Runko could find or conclude differently when conducting the ORI review as he was reviewing his own work. However, the regulations do not require that the ORI review and investigation be done by someone not involved in the institution's investigation or one who is neutral or impartial. Respondent's concern regarding Runko's objectivity is well-founded. Runko's involvement in both the WSU Investigation and the ORI review and investigation is considered when judging the weight and credibility of the ORI findings and charges. ORI failed to establish Runko's actual qualifications, which presents significant challenges when judging his credibility and the weight to give his testimony and the

evidence he created. ORI did not explain for me what a “Scientist-Investigator” is or more importantly, explain what qualifications Runko had to do the data analysis and investigation he did for ORI. Runko did not list his qualifications in his declaration (ORI Ex. 69) or provide a curriculum vitae or resume. ORI asked no questions at hearing about his qualifications. Tr. 82-84. Generally, it would be extraordinarily difficult to assess the credibility of Runko’s findings and conclusions absent some evidence of how he was qualified to make those findings and conclusions. Respondent elicited on cross-examination that Runko began working at ORI in November 2010 and he was assigned to the WSU Investigation in mid-2011. Tr. 85. However, Respondent did not specifically object to Runko’s qualifications or lack thereof. Because no objection was raised regarding Runko’s qualifications, the matter was not addressed further at hearing. I accept that Runko did the analysis he represents he did on behalf of ORI and that his findings are the bases for the ORI charges. However, without clarity regarding Runko’s qualifications, I choose not to rely upon Runko’s findings and conclusions. I examine the evidence more closely than might otherwise have been required if Runko’s qualifications were established by the evidence. And, as required, I render findings and conclusions de novo without accepting Runko’s opinions as those of a qualified expert.

I find it unnecessary to summarize or analyze in detail the reports, findings, and conclusions of either the VA or ORI. I am tasked to provide Respondent with an independent de novo review of the ORI findings of research misconduct and the proposed administrative actions. It is not for me to review the WSU, the VA, or the ORI proceedings. My task is to review the evidence presented to me to determine whether or not that evidence establishes that Respondent committed research misconduct. I will not consider whether WSU, VA, or even ORI correctly accomplished their statutory and regulatory tasks as required by the regulations or whether their findings of research misconduct were correct. I review the charges of research misconduct anew.

b. Respondent’s whistleblowing at WSU does not adversely impact the ORI charges which are subject to de novo review in this forum.

It is also necessary as a preliminary matter to address an issue that Respondent argues is pervasive in this case and affects the credibility of the charges and the evidence. Respondent has argued consistently that the charges of research misconduct were fabricated and made in retaliation for Respondent blowing the whistle on WSU for mismanagement of its grants. Specifically, Respondent asserts that in June 2011, a report was delivered to WSU that “he authored [in part] . . . in which the university’s grant reconciliation practices were put under scrutiny regarding obtaining funds in a fraudulent manner.” R. Reply at 29; RFH at 3; R. Ex. 22; Tr. 258-82, 349-56. Respondent’s evidence shows that he was selected to be part of a “Task Force for Streamlining Processes” at WSU (Streamlining Task Force or task force) along with ten others. R. Ex. 22 at 1. The report of the task force states that the task force was formed on March 3,

2011, and given the mission to “identify and examine systemic issues that impact the operational efficiency of [WSU].” R. Ex. 22 at 2. Respondent testified that he was solicited by the Provost to be on the task force as early as December 2010 and the announcement of the task force was made in January 2011. Tr. 281, 349.

On February 10, 2011, 21 days prior to the official formation of Streamlining Task Force, the WSU Research Integrity Officer met with Christian Reynolds (Complainant) who in a letter dated “February 8, 2010”¹⁶ made research misconduct complaints against Respondent. ORI Ex. 1 at 6. The WSU research misconduct inquiry and investigation against Respondent began on about March 1, 2011, when the WSU Inquiry Committee first met to consider allegations of research misconduct against Respondent, two days before the official formation of the Streamlining Task Force. On March 10, 2011, the Inquiry Committee recommended a research misconduct investigation, seven days after the task force was officially formed with Respondent as a member. ORI Ex. 21 at 2. The WSU Investigation Committee convened on April 5, 2011. ORI Ex. 1 at 3-4, 6.

The final report of the Streamlining Task Force, titled “Task Force for Streamlining Processes” was dated June 27, 2011, 137 days after the WSU Research Integrity Officer met with the Complainant and 118 days after the WSU research misconduct investigation against Respondent began. The task force report does not show the task force was given the specific mandate to investigate grant procedures. Indeed, my reading of the task force report in evidence as R. Ex. 22 does not reflect any clear allegation of research/grant fraud. Further, the report does not attribute particular findings to any of the eleven task force members by name. Respondent testified that he drafted the section of the report titled “Sponsored Program Administration (SPA).” R. Ex. 22 at 5-6; Tr. 279-81. I find no overt allegation of grant fraud in the section Respondent drafted. It is suggested in the report that WSU may interpret federal guidelines regarding disallowable costs too strictly. The report also suggests some possible irregularities at WSU based on interpretation and/or application of applicable federal regulations related to effort reporting. R. Ex. 22 at 6. I find in the passage Respondent drafted no specific allegation of grant fraud or any misconduct related grant administration.

¹⁶ It has not been shown whether the letter was actually dated February 8, 2010, more than a year before the Research Integrity Officer met the Complainant, or whether “2010” is a typographical error. The date of the Complainant’s letter does not affect the recommended decision in this case. The date of receipt of the complaint by WSU triggered the running of the six year period of limitations under 42 C.F.R. § 93.105(a), but none of the ORI charges exceed the six-year limitation. The letter is not in evidence before me and the unknown content of that letter has no impact upon my decision.

Based on the chronology and the Streamlining Task Force's report, any assertion that the WSU research misconduct investigation was initiated in retaliation for Respondent's allegations of improprieties with grant funds reported in the June 27, 2011 task force report is simply not credible.

The WSU Investigation of Respondent was completed November 30, 2011. ORI Ex. 1 at 3-6. The WSU Investigation findings were released after the Streamlining Task Force report was released. The sequence of the release of the reports shows it is possible that the WSU Investigation findings could have been affected by the Streamlining Task Force report. I consider the inference in assessing the probative value and weight of the evidence and the allegations of research misconduct, being cautious to look for any evidence of such impact. However, I do not rely upon the findings and conclusions of the WSU Investigation, the ORI review, or as discussed hereafter, the work and opinions of Runko. I am required by law to provide Respondent an independent de novo review of the ORI findings of research misconduct and the administrative actions proposed by ORI. I do not have authority, and I am not required to review the WSU procedures or misconduct findings or the ORI research misconduct review. 42 C.F.R. § 93.517(b). However, to the extent that the underlying misconduct findings and evidence upon which they are based may be tainted by bias, prejudice, or self-interest, I am obliged in providing de novo review to consider any evidence to that effect in judging the probative value and weight of any evidence potentially tainted.

Respondent asserts in his request for hearing that retaliation was also due to the fact that he filed a federal False Claims Act (31 U.S.C. §§ 3729-3733) *qui tam* suit alleging grant fraud by WSU and University Physician Group; retaliatory discharge; and defamation. But Respondent did not file his *qui tam* suit until October 31, 2012, 11 months after the WSU research misconduct investigation was completed. The federal district court dismissed the suit on grounds WSU was not a "person" under the False Claims Act and was entitled to sovereign immunity as an arm of the state under the Eleventh Amendment to the U.S. Constitution. On December 4, 2015, the Sixth Circuit Court of Appeals upheld the dismissal by the district court. RFH, R. Exs. 7-8 (DAB E-File Items # 1, 1h-1i); *U.S. ex rel. Kreipke v. Wayne State Univ. & Univ. Physician Group*, 807 F.3d 768 (2015). Respondent filed a petition for writ of certiorari on May 19, 2016, that was denied on January 9, 2017. *Kreipke v. Wayne State Univ.*, __ U.S. __, 137 S. Ct. 617 (2017). I note that the WSU Investigation against Respondent began on about March 1, 2011, when the Inquiry Committee first met, and the investigation was completed by November 30, 2011. ORI Ex. 1 at 3-6. Because the WSU research misconduct investigation began 19 months before and was completed 11 months before Respondent filed his *qui tam* suit, Respondent's allegation that the charges of research misconduct leveled by WSU were in retaliation for the filing of the *qui tam* suit is not credible.

Judge Moran indicates in her decision in *Christian Kreipke v. Dep't of Veterans Affairs*, Docket Number CH-1221-15-0284-W-1, that in August 2010, Respondent reported to

WSU management the fraudulent use of indirect costs and disallowable costs by WSU. R. Ex. 21 at 3-4. Judge Moran does not discuss the factual basis for the finding. I am not bound by Judge Moran's finding and without some discussion of the evidence upon which she based her finding that shows Respondent made such a report, I decline to consider Judge Moran's finding as evidence of whistleblowing for which there may have been retaliation. Respondent did produce evidence of email communication between him and Rafols dated August 17, 2010, complaining about "disallowable costs." R. Ex. 23 at 1. The email does not indicate that Respondent made an allegation of fraud to or against WSU that may have been the basis for retaliation. Similarly, an email on June 14, 2010, between Respondent and another individual shows he refused to "sign off" on an "effort report" because he felt it was wrong. R. Ex. 23 at 2. But this email also is not evidence that Respondent reported fraud by or to WSU. Respondent did not specifically assert in testimony that he believed that his refusal to sign or approve an effort report and his complaints about disallowable costs in August 2010, constituted complaints of fraud by or to WSU. Tr. 272-79. Rather, Respondent implies that his actions were part of the overall situation that led to his appointment to the Streamlining Task Force and ultimately retaliation for his participation in that task force.¹⁷ Tr. 274, 279, R. Ex. 22.

The research misconduct regulations require that institutions respond to allegations of research misconduct in a "thorough, competent, objective and fair manner, including precautions to ensure 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." 42 C.F.R. §§ 93.300(b), 93.304. The regulations do not permit me to inquire as to the existence of conflicts or provide specific relief in the event of conflicts. 42 C.F.R. § 93.517(a)-(b). However, I am obliged to judge the credibility of documents and testimony and their probative value and weight, and I do so in according Respondent de novo review.¹⁸

¹⁷ A real "head scratcher" is why Respondent was even appointed to the Streamlining Task Force on about March 3, 2011, given that the research misconduct inquiry and investigation began a couple days before the formal beginning of that committee on March 3, 2011. R. Ex. 22 at 2. It is also difficult to rationalize why WSU appointed Respondent to the task force if at the same time it was retaliating against him for his complaints about effort reporting and disallowable costs or some other actual or perceived allegations of fraud by WSU or its researchers.

¹⁸ In the MSPB decision by Judge Moran discussed hereafter, it is clear that she was concerned by at least the appearance of a conflict of interest involving the VA and WSU. She stated: "I find the existence and motive to retaliate [against Respondent] stemmed from the improper influence of WSU over the VA to take action against the

c. Respondent's whistleblowing and the finding of retaliation at the VA by MSPB Judge Moran have no impact upon the ORI charges which are subject to de novo review in this case.

It is necessary to consider further the impact of the March 10, 2017 decision of Dorothy L. Moran, Administrative Judge, sitting for the MSPB in the case of *Christian Kreipke v. Dep't of Veterans Affairs*, Docket Number CH-1221-15-0284-W-1. R. Ex. 21.

Respondent filed that action alleging the VA terminated him from his job at the VA on October 11, 2013, in retaliation for his whistleblower activity. Respondent argued in his suit that the VA retaliated by terminating him or not renewing his appointment, failing to compensate him, and barring him for ten years from VA employment. Judge Moran found jurisdiction under the Whistleblower Protection Act, 5 U.S.C. § 1221(a). Six days of trial were conducted. R. Ex. 21 at 1-2. The specific issues that Judge Moran stated she was authorized to decide are set forth at page 8 of her decision. R. Ex. 21 at 8. Judge Moran did not state that she had jurisdiction to decide whether or not Respondent committed research misconduct at the VA. Judge Moran explained that if Respondent met his burden before her to show by a preponderance of the evidence that "his protected disclosures were a contributing factor in the agency's personnel actions, then . . . the agency . . . must show by clear and convincing evidence that it would have taken the same personnel actions even if [Respondent] had not made a disclosure." R. Ex. 21 at 9. She explained that in order to determine whether the agency met its burden, it was necessary for her to consider "the strength of the evidence the agency used in support of the personnel action," among other factors. R. Ex. 21 at 9. Because the VA relied upon its findings of research misconduct by Respondent at the VA in support of its challenged personnel action against Respondent, Judge Moran found that she was obliged to consider the VA research misconduct proceedings. R. Ex. 21 at 9, 18-37.

Judge Moran found that Respondent held a dual appointment as an Assistant Professor at WSU and as a scientist at the VA, and payment of his salary was split between the two.¹⁹

[Respondent]." R. Ex. 21 at 37. Judge Moran does not specifically explain why WSU influenced the VA to retaliate against Respondent, but she clearly points to at least the appearance of a conflict on the part of WSU. Because I have no authority to examine whether or not the WSU research misconduct proceedings were tainted, I render no opinion as to whether the ORI regulations prohibit even the appearance of a conflict and should have disqualified WSU and its staff from conducting the research misconduct proceedings against Respondent.

¹⁹ The arrangement is described by Dr. Kaatz in his deposition. Dr. Kaatz stresses that Respondent's work at the VA had to be completely separate from his work at WSU for

Judge Moran states in her opinion that Respondent testified that on June 14, 2010, he refused to sign or approve an effort report presented to him by a WSU official that over-reported his effort and would have enabled WSU to receive more federal grant money. Judge Moran also found that in August 2010, Respondent reported to WSU management the fraudulent use of indirect costs and disallowable costs by WSU. R. Ex. 21 at 3, 10. Judge Moran found the evidence sufficient to meet Respondent's burden to show he had made protected disclosures under the Whistleblower Protection Act. R. Ex. 21 at 12. Judge Moran states that in 2011 WSU appointed Respondent to an internal committee to investigate grant procedures; he presented his portion of the written report on June 29, 2011, in which he reported that WSU was likely engaging in research/grant fraud; and thereafter allegations of research misconduct regarding a particular grant surfaced at Respondent's laboratory. R. Ex. 21 at 4. Judge Moran does not specifically state what internal committee Respondent was appointed to. But it is more probable than not that she was referring to Respondent's selection with ten others for participation as a member of the WSU Streamlining Task Force. R. Ex. 22 at 1. The task force was formed on March 3, 2011, and given the mission to "identify and examine systemic issues that impact the operational efficiency of [WSU]." R. Ex. 22 at 2. Respondent's evidence does not show the task force was given the specific mandate to investigate grant procedures. Indeed, my reading of the task force report in evidence as R. Ex. 22 does not reflect any clear allegation of research/grant fraud. Further, the report does not attribute findings to any of the eleven task force members by name. At most, the report suggests some possible irregularities at WSU based on interpretation and/or application of applicable federal regulations. R. Ex. 22 at 6. Therefore, I give little weight to Judge Moran's finding that Respondent was on an internal committee at WSU investigating research/grant fraud. Judge Moran also suggests that allegations of research misconduct were made against Respondent at WSU after June 29, 2011; however, as already discussed, the evidence before me shows the allegations were actually made in February 2011 before the task force was officially formed and before the task force issued its report. Judge Moran states that in February 2011, WSU notified Dr. Kaatz, Assistant Chief of Staff for Research & Development at the VA and a Professor of Internal Medicine at WSU, of research misconduct allegations against Respondent at the VA. R. Ex. 21 at 4. The timing is consistent with the evidence before me that shows Reynolds made a complaint of research misconduct against Respondent to WSU in February 2011. ORI Ex. 1 at 6. Judge Moran states in her decision that Dr. Kaatz explained that WSU and the VA collaborate on research misconduct and that WSU is the academic partner of the VA with many VA employees having a WSU appointment. According to Judge

his joint appointment to be valid. Respondent had a NIH grant he worked on at WSU while he worked under a VA grant at the VA. R. Ex. 17 at 3-4.

Moran, Dr. Kaatz determined in March 2011 that there was insufficient evidence of research misconduct by Respondent and did not refer the matter for further investigation. R. Ex. 21 at 4. In April 2011, WSU contacted the VA regarding an allegation of salary fraud against Respondent and again, according to Judge Moran, Dr. Kaatz determined there was insufficient evidence to refer for further investigation.²⁰ R. Ex. 21 at 4-5. Judge Moran found that WSU ultimately completed an investigation of Respondent in December 2011, concluding that Respondent engaged in research misconduct. R. Ex. 21 at 5. The evidence before me establishes that the WSU Investigation was actually completed on November 30, 2011. ORI Ex. 1. Judge Moran found that Respondent was terminated by WSU on February 29, 2012, but Respondent continued his VA employment. In April 2012, WSU again contacted the VA about the same research misconduct allegations WSU investigated. On this occasion the allegations were not referred to Dr. Kaatz but to an acting research integrity officer who determined to refer the allegations for further investigation.²¹ Judge Moran found that in August 2012, Respondent made allegations of grant fraud against both the VA and WSU to VA headquarters. R. Ex. 21 at 5. The VA research misconduct investigation concluded that Respondent engaged in research misconduct and administrative actions were

²⁰ Judge Moran's fact finding is at odds with the deposition taken in connection with the MSPB case. Dr. Kaatz explained in his deposition taken in connection with the MSPB case, that in February 2011 he reviewed the allegations from WSU and determined that it did not appear VA resources were involved in the allegations and the VA elected not to get involved with the WSU Investigation. His analysis was that the challenged publications predated Respondent's VA grant. In June 2011, Dr. Kaatz was tasked to review an Office of Inspector General (OIG) complaint he later learned was made by Christian Reynolds. The OIG complaint related specifically to the VA grant and the allegation that the grant was awarded under false pretenses. Dr. Kaatz apparently believed that the June 2011 complaint involved VA funds and conducted a preliminary investigation. Dr. Kaatz gathered evidence, spoke with Rafols and others, obtained information from Respondent's notebook, and recalculated the data, arriving at very similar results to those of Respondent that appeared in the questioned grant. After more than 100 hours of work, Dr. Kaatz reported in July 2011 that there was insufficient evidence for a referral for a full investigation of the research misconduct allegations against Respondent. Dr. Kaatz was very specific that he made no finding whether or not research misconduct occurred – only that there was insufficient evidence to refer the matter for a full investigation. R. Ex. 17 at 6-11.

²¹ Dr. Kaatz is clear in his deposition that when the third allegation came in May 2012, he recused himself because of his prior involvement in the June 2011 inquiry and on advice of the VA ORO. R. Ex. 17 at 15-16. Thus, the evidence does not support an inference of some inappropriate manipulation of Dr. Kaatz's involvement by the VA.

recommended. Respondent was notified that his VA appointment would expire on October 11, 2013, and he was barred from receiving VA research funds for ten years. R. Ex. 21 at 6-7.

Judge Moran's analysis shows that the standards she applied are significantly different from those established by 42 C.F.R. pt. 93, which control in the case before me. Judge Moran examined the VA research misconduct proceedings to determine whether the VA showed by clear and convincing evidence that it would have taken the personnel actions against Respondent absent Respondent's whistleblowing activity. She concluded that the VA did not meet its burden. R. Ex. 21 at 17. Judge Moran identified that the VA research misconduct charges against Respondent involved falsification of medical research, and she opined that the evidence did not "clearly and convincingly support its finding that it was the [Respondent's] actions that resulted in 'falsifying' medical research." R. Ex. 21 at 23. Judge Moran stated that under the policy and case law applicable in the VA research misconduct case, the VA had to show that the information submitted included a false statement, the false statement was material, and the employee had the required intent. Further, Judge Moran concluded that the VA had to show that Respondent intended to deceive or mislead the agency, and he intended to defraud the agency for his own private material gain. R. Ex. 21 at 23. These are all higher standards than those required under 42 C.F.R. pt. 93, both as to the quantum of evidence required under 42 C.F.R. pt. 93 (clear and convincing versus a preponderance of the evidence) and as to the intent element (the VA must show specific intent to cause a result while ORI regulations require only a showing of general intent to do an act). Judge Moran found no VA testimony or evidence that a falsification occurred related to the one VA grant Respondent held and no evidence that any falsified data or graphs were prepared at the VA. She found that all experiments alleged to result in falsified data occurred at WSU not the VA. Judge Moran found that the VA did not show "what harm the agency suffered or gain to the [Respondent] occurred." R. Ex. 21 at 27. Neither harm to the agency or gain to Respondent is a required showing under 42 C.F.R. pt. 93. Judge Moran found that "although the agency found [Respondent's] falsification was willful and intentional, the record shows that [Respondent] had been lax in his oversight of the lab and that the inaccuracies could have been inadvertent. It is important to note that [Respondent] moved quickly to correct the inaccuracies." R. Ex. 21 at 29. Judge Moran concluded that the VA failed to show Respondent intended to deceive or mislead the agency and failed to show that Respondent intended to defraud the agency for his own private material gain. R. Ex. 21 at 30. Judge Moran ultimately concluded that the VA did not meet its steep burden to show Respondent's termination had causation independent from Respondent's whistleblower status. She also concluded that the VA created a hostile work environment for Respondent which he established by a preponderance of the evidence. R. Ex. 21 at 38-39. Judge Moran ordered the VA to take corrective actions. But she determined that further proceedings were necessary to determine exactly what corrective actions were appropriate to accord Respondent relief. R. Ex. 21 at 41.

I conclude that Judge Moran's decision has little or no impact upon the case before me. The issues before Judge Moran were different than those before me. Judge Moran applied different legal standards than those applicable in this forum. Judge Moran found it necessary to examine the VA research misconduct proceedings and findings, but for the purpose of deciding whether the findings of research misconduct at the VA were clear and convincing evidence that the VA would have taken action against Respondent based on those findings without consideration of his whistleblowing activities. Judge Moran limited her inquiry to the single VA grant Respondent possessed and to his conduct that occurred at the VA rather than WSU. I note that Judge Moran found Respondent a credible witness. R. Ex. 21 at 27. However, Judge Moran's findings are not binding in this proceeding and she did not enter findings that resolve the issues before me related to Respondent's alleged research misconduct at WSU.

d. Unsworn statements from the WSU Investigation are entitled to lesser weight than sworn testimony.

The record contains several documents that are transcripts of interviews conducted as part of the WSU Investigation. ORI Exs. 64-65, R. Exs. 25-26, 30-31. Cunningham testified before me that none of the interviews conducted by the WSU Investigation committee were under oath or affirmation or any other warning that the interviewees were obliged to tell the truth.²² Tr. 157-58. Pursuant to 42 C.F.R. § 93.518(a), witnesses must give testimony at the hearing under oath or affirmation. Pursuant to 42 C.F.R. § 93.518(b), an ALJ may admit written testimony, including prior sworn testimony that was subject to cross-examination, if the witness is available at the hearing for cross-examination. In order to qualify as "testimony" under 42 C.F.R. § 93.518(a), the person who makes the statement must have committed to tell the truth and be subject to sanction for failing to tell the truth. I construe 42 C.F.R. § 93.518(b) which refers to "written testimony" to require, consistent with 42 C.F.R. § 93.518(a), that the person who gave the statement also committed to tell the truth or be subject to penalty for failing to do so. Therefore, unsworn statements, whether written by the declarant or transcribed from an interview, do not qualify as "testimony" under 42 C.F.R. § 93.518, unless the declarant promised to tell the truth subject to penalty for failing to do so. Therefore, I conclude that the unsworn statements from the WSU Investigation do not qualify as testimony and may not be weighed as or given the probative value of sworn testimony. The ALJ is required to admit evidence unless it is clearly irrelevant, immaterial, or unduly repetitious. 42 C.F.R. § 93.519(c). However, evidence may be excluded even if relevant and material if its probative value is substantially outweighed by the danger of unfair prejudice. *Id.* The

²² The notary certificates for ORI Ex. 64 and R. Ex. 26 indicate an oath was administered by the notary, but I accept Cunningham's testimony that none of the interviews during the WSU Investigation were conducted under oath.

unsworn statements, which are offered by both ORI and Respondent, are part of the WSU Investigation and are relevant and their admission is thus required. Any weight accorded those documents is discussed hereafter as part of my Analysis.

e. The complaint and allegations of the Complainant have not been presented as evidence and are entitled to no weight.

The Complainant met with the WSU Research Integrity Officer on February 10, 2011, to discuss allegations of misconduct against Respondent. There is no dispute that the Complainant was Christian Reynolds, a former graduate student in Respondent's laboratory. ORI Ex. 1 at 6, 36; ORI Ex. 52; R. Br. at 26; Tr. 107-09. There is no question that Respondent was never given a copy of Reynolds' letter that leveled the complaint against Respondent and no copy is in the record before me. Tr. 109-112, 288, 375. There is also no question that Respondent was not permitted to confront Reynolds during the WSU Investigation.²³ ORI Ex. 52 at 2-4. The WSU Investigation conducted an interview of Reynolds; only a portion of his unsworn interview is in the record before me. ORI Exs. 1 at 9, 43; 52 at 20, 23-27, 30-33. Cunningham agreed that during his interview, Reynolds stated that everyone in the laboratory had access to the computers in the laboratory. Tr. 114-18. The extract of the interview of Reynolds is consistent with Cunningham's testimony. The interview shows that Reynolds had access to the computer in Respondent's office. The evidence before me does not show whether Reynolds was questioned about his possible malice toward Respondent or whether he engaged in altering documents on computers in the laboratory or loading files to the computer in Respondent's office in order to implicate Respondent in research misconduct, as Respondent suggests. ORI Ex. 52 at 24-25, 38; Tr. 134.

The evidence shows allegations of threats of harm by Reynolds against Respondent. ORI Exs. 1 at 35; 63; Tr. 151, 215, 604. In fact, Respondent in August 2011 obtained a Personal Protection Order (PPO) against Reynolds based on threats against Respondent. Respondent testified before me that the threats included cutting his brake line, and placing his hands in liquid nitrogen. Respondent testified that a gun manual was found on Reynolds' desk. Respondent testified that the PPO was upheld at a hearing when

²³ ORI regulations do not establish due process rights for the respondent to be present during the institution's investigation, to see the evidence relied upon, or to confront and cross-examine witnesses. Rather, a respondent is given an opportunity to comment upon the investigation report with supervised access to the evidence on which the report is based. 42 C.F.R. § 93.310, 93.312. The rights to participate, to have counsel, to see the documentary evidence, and to examine and cross-examine witnesses are first accorded when a respondent timely requests a hearing before an ALJ. Respondent in this case did not demand production of the complaint or Complainant before me.

Reynolds admitted he threatened Respondent. Respondent testified that a WSU lawyer subsequently sent the judge an ex parte communication regarding the WSU Investigation suggesting that Respondent was trying to retaliate against Reynolds for reporting Respondent had engaged in research misconduct. Tr. 604-608. ORI submitted the transcript of the second PPO hearing for my consideration. ORI Ex. 63. The transcript shows that on October 13, 2011, Judge Elder, Circuit Court of Wayne County, Michigan, terminated the PPO that Respondent had obtained against Reynolds on August 23, 2011. Judge Elder admitted that during the prior hearing, which was a hearing on Reynolds' request to terminate the PPO, Reynolds had given her the letter about the WSU Investigation, but she had not read the whole letter. Thus, contrary to Respondent's assertion, it does not appear that there was an ex parte communication between a WSU official or attorney and Judge Elder, though it is not clear that Judge Elder shared the letter with Respondent. The transcript of the hearing shows Respondent was present during the hearing because he spoke to Judge Elder on the record. Judge Elder admitted that at the prior hearing, she simply heard the parties and upheld the PPO, without reading the letter completely. Judge Elder stated that she subsequently read the letter and then convened the hearing on October 13, 2011. ORI Ex. 63 at 3-5. Judge Elder stated that based on the letter she found Respondent was not credible and his application for the PPO seemed retaliatory, and Judge Elder withdrew the PPO. ORI Ex. 63 at 5, 7-9, 13, 16-18, 22-23. Respondent testified before me that he was particularly concerned about the termination of the PPO because he was working at the VA at the time "in close proximity" to Reynolds. Tr. 607-08. Respondent's testimony suggesting that he worked in close proximity to Reynolds is at odds with evidence before Judge Elder that Reynolds was no longer living in the Detroit area even though there is some evidence Reynolds had been seen on the WSU campus at some unspecified time. Further, the transcript of the hearing before Judge Elder does not show that Respondent or his attorney told Judge Elder that there was concern that Respondent's work at the VA placed him in close proximity to Reynolds, a fact that may have affected Judge Elder's ruling and her perception of Respondent as being not credible. ORI Ex. 63 at 9, 20, 23-24.

According to the report of the WSU Investigation, Reynolds alleged that Respondent misrepresented figures and data published in a special edition of the journal *Neurological Research*. The WSU Investigation found "several additional instances of misrepresentation . . . involving at least five published manuscripts, 14 NIH grant proposals and numerous public presentations that extended" the WSU Investigation beyond the complaint. ORI Ex. 1 at 36. Thus, the WSU Investigation expanded beyond the complaint.

Respondent testified that he told the WSU investigators that there needed to be examination of Rafols and Reynolds, particularly because he was suspicious of finding Reynolds and another person who had been fired from the laboratory doing something with the computer in Respondent's office on about February 6, 2011. Tr. 658-59, 798-99, 822-23, 828-30; ORI Ex. 52 at 8. Respondent agreed with me that raising suspicion

about Rafols and Reynolds is part of his defense in this case. Tr. 564, 723-25, 798-99. Respondent's theory is that everyone in the laboratory had access to all the computers in the laboratory and most anyone could have made changes to images that are the bases for the ORI allegations of misconduct. Tr. 727, 822-23.

Pursuant to 42 C.F.R. § 93.506(b)(5), I have the authority to compel the attendance of witnesses at a hearing though the mechanism for compelling attendance is not clear. The regulations are not clear whether there is authority for the issuance of a subpoena in the name of the Secretary, the usual method for compelling attendance. 42 C.F.R. pt. 93, *see e.g.* Social Security Act § 205(d)-(e) (42 U.S.C. § 405(d)-(e)). The Administrative Procedure Act, 5 U.S.C. § 551 *et. seq.*, only authorizes the issuance of subpoenas authorized by law. 5 U.S.C. § 556(c). However, I need not resolve whether or not I am authorized to issue subpoenas as neither ORI nor Respondent requested that I attempt to compel Reynolds' attendance at hearing by order, subpoena, or otherwise.

The fact that Reynolds was not called by ORI as a witness in this case prevents my consideration of any evidence related to the Reynolds' original complaint and the bases for the complaint. I have had no opportunity to observe Reynolds and judge his credibility. Because the original complaint is not before me, I have no need to weigh its credibility. Because Reynolds is not a witness before me, I have no need to judge his credibility.

f. The absence of testimony by Jose Rafols, Ph.D., Respondent's mentor and supervisor, raises serious issues about the completeness and objectivity of the WSU Investigation and the completeness of the ORI investigation, which is based on the WSU Investigation, but does not prevent de novo review of the ORI research misconduct charges against Respondent and the evidence that ORI has presented.

The WSU Investigation indicates Respondent worked for Rafols as a research assistant from November 22, 2004 until November 14, 2008. Respondent was appointed an Assistant Professor (Research) on November 15, 2008, and to a tenure-track position as Assistant Professor in the Department of Anatomy and Cell Biology on November 30, 2009. The WSU Investigation found that the earliest instances of misrepresented data were published in a paper in 2006 and other instances occurred while Respondent was a research assistant in Rafols' laboratory and an assistant professor. However, Respondent took over the laboratory on about October or November 2009, and the latest alleged instance of scientific misconduct occurred in 2011. ORI Ex. 1 at 36-37; ORI Ex. 52 at 5, 16.

Cunningham testified that he knew that Rafols was the expert in histology and he would normally be responsible for capturing the Fluoro-Jade and western blot images at issue in

the WSU Investigation. Cunningham agreed that there were five attempts to interview Rafols, but he simply refused. Tr. 123-24. Cunningham agreed that Rafols was also not formally interviewed as part of the VA investigation. Tr. 126-27; ORI Ex. 52 at 34.

Respondent testified that he did suggest to the WSU Investigation that there needed to be examination of Rafols. He agreed that raising suspicion about Rafols and Reynolds is part of his defense in this case. Tr. 564. Dr. Kaatz spoke with Rafols and exchanged email with him. R. Ex. 17 at 5. Dr. Kaatz testified at his deposition in the MSPB case that Rafols told him: that while Respondent was in doctorate training they had meetings; he had full and complete confidence in Respondent's ability; and that he felt any data Respondent presented to him that he reviewed, he would have considered the data authentic. R. Ex. 17 at 13. Unfortunately, Dr. Kaatz did not testify that he reviewed with Rafols the data and images that underlie the WSU research misconduct allegations. However, Dr. Kaatz testified that he did attempt to verify some data Respondent used that was in laboratory notebooks, and while there was not an exact match, it was close. R. Ex. 17 at 9, 13. Neither party attempted to produce either Rafols or Dr. Kaatz as witnesses before me.

Respondent suggests that Rafols could be responsible for at least part of the false or fabricated research material attributed to Respondent. R. Br. at 9-11, 16-17, 20-21, 26; R. Reply at 22-26. However, as Respondent correctly notes, Rafols was not interviewed as part of the WSU Investigation and Rafols' potential role in the research misconduct attributed to Respondent was not actually investigated. Cunningham's testimony regarding why Rafols was not interviewed was simply that Rafols declined to be interviewed and apparently under the WSU investigative protocols and authority, WSU had no ability to compel an interview. Tr. 180, 186-87. While there may have been evidence to implicate Rafols, for example, the fact that he had supervisory responsibility for the laboratory and that many of the documents in question listed Rafols as a Principal Investigator (PI) or first author, WSU made the determination not to add Rafols as a respondent. Cunningham's explanation in response to my questioning about why Rafols was not also investigated is unsatisfactory. Tr. 179-83. Cunningham testified that he looked at five years of Rafols' publications prior to Respondent joining his laboratory and found no evidence of research misconduct. He testified that the research misconduct was identified as occurring two years after Respondent joined Rafols' laboratory and it did not appear that Rafols was implicated in the instances of research misconduct under investigation. Tr. 180-83. Cunningham provided no explanation for how he could simply look at prior publications of Rafols and decide there was no evidence of any research misconduct. Cunningham's explanations for not investigating Rafols are neither reasonable nor credible given Rafols' involvement in the laboratory and that he was listed as the PI or first author on some of the grants or publications that are the bases for the ORI charges in this case. Neither ORI nor Respondent sought to compel Rafols to appear and testify at the hearing before me, but I accept that neither could be certain of what

Rafols might say or perhaps they determined I have no authority to compel attendance of a witness under 42 C.F.R. pt. 93.

The VA report of investigation states:

The committee requested an interview, at his convenience, with Dr. Jose Rafols, Professor of Anatomy and Cell Biology, Wayne State University School of Medicine and former mentor of and collaborator with the respondent. AIB [Administrative Investigation Board] members strongly believed that he could provide invaluable and unique insights resulting from his relationship with the Respondent that could facilitate the efficient performance of the investigation. However, Dr. Rafols declined to be interviewed by the committee.

ORI Ex. 58 at 4 (italics in original).

The absence of testimony or at least a statement by Rafols poses a real challenge for deciding some of the allegations of research misconduct in this case. There is evidence of Rafols' involvement in various questioned publications, that he had some responsibility for the laboratory, that his specialty was histology, which is the specialty to which some of the questioned materials related and in which Respondent was not qualified. Additionally, Rafols resisted being interviewed in either the WSU or the VA investigations. It is true that ORI need only show that it is more likely than not that research misconduct was committed by Respondent. However, the evidence of potential involvement by Rafols must certainly be weighed in determining whether ORI has made a prima facie showing as to each charge.

g. The reports of the investigations by the VA (ORI Ex. 58) and WSU (ORI Ex. 1) are entitled to little or no evidentiary weight on the issue of whether Respondent committed research misconduct.

The VA research misconduct findings were marked and admitted as ORI Ex. 58. There are numerous references in the VA findings to exhibits, but none were included in ORI Ex. 58. The VA investigation is given little or no weight because it is not possible for me to weigh that report as evidence without the opportunity to view and weigh the evidence upon which the findings, conclusions, and opinions in the investigation report are based. Respondent did not object to admission of ORI Ex. 58. However, there is little evidence before me about the VA investigation or how it was conducted. I also have no evidence that shows why Paula Dore-Duffy, Ph.D., one of the witnesses in the VA investigation whose affirmed testimony has been placed in evidence in this proceeding by ORI as ORI

Ex. 66, was not also subject to investigation for research misconduct given her status as the first listed author on an article that was alleged to include false images (ORI Exs. 12; 67 at 7). I conclude that the findings, conclusions, and opinions set forth in the VA investigation report are entitled to minimal or no weight.

The WSU Investigation report was marked and admitted as ORI Ex. 1. The WSU Investigation report lists exhibits 1 through 70, but ORI did not file those exhibits as part of ORI Ex. 1. ORI Ex. 1 at 42-43. I conclude that the report of the WSU Investigation, including the findings, conclusions, and opinions stated therein, is entitled to little evidentiary weight. The report reflects that the WSU Investigation found Respondent engaged in research misconduct. But without the ability to review the evidence upon which the WSU Investigation based its findings and conclusions, I cannot judge the credibility, determine probative value, or weigh the findings and conclusions of the WSU Investigations as substantive evidence in support of the ORI charges.

3. Respondent engaged in research misconduct.

a. What are the charges?

Before turning to the specific charges²⁴ of misconduct, it is instructive to consider how ORI characterizes the charges in the charge letter and the overall ORI approach to proving the charges.

ORI summarized its findings of research misconduct in the charge letter. ORI states that it found by a preponderance of the evidence that Respondent:

- (1) Either “intentionally, knowingly, or recklessly;”
- (2) “[R]e-used and falsely labeled images and graphs;”
- (3) “[R]e-used and falsely labeled images and graphs” were used in:
 - (a) PHS/NIH grant applications (6 unfunded and 1 funded);
 - (b) 3 publications;

²⁴ In the charge letter, ORI labels each charge as an “ORI Issue.” To be clear in this decision I use the term “charge” which is the term used in 42 C.F.R. pt. 93. 42 C.F.R. §§ 93.202, 93.313(c), 93.405. References to “ORI Issue” in the charge letter (ORI Ex. 67) should be read as “ORI Charge.” The charge letter lists ORI Charges 1, 1a, 1b, 1c, 1d, 2, 2a, 2b, 3, 3a, 3b, 4, 4a, 4b, 4c, 4d, and 5, a total of 17 charges. ORI Ex. 67 at 16-35.

- (c) 5 posters; and
- (d) 1 book; and

(4) Respondent used falsified images and graphs in grant applications, publications, posters, and a book 64 times.

ORI Ex. 67 at 1.

In ORI Charge 1, it is alleged that Respondent falsely reported by reusing and falsely labeling images. In ORI Charge 1a it is alleged that Respondent reused a single image to represent two different things. ORI Ex. 67 at 16. In ORI Charge 1b it is alleged that Respondent reused an image to represent two different things. ORI Ex. 67 at 18. In ORI Charge 1c it is alleged that Respondent reused an image to represent three different things. ORI Ex. 67 at 20. In ORI Charge 1d it is alleged Respondent reused an image to represent something different in one grant application. ORI Ex. 67 at 22.

In ORI Charge 2 it is alleged that Respondent reported falsely by reusing and falsely labeling an image to represent different things. In ORI Charge 2a it is alleged that Respondent reused an image to represent two different things. ORI Ex. 67 at 24. In ORI Charge 2b it is alleged Respondent reused an image to represent three different things. ORI Ex. 67 at 25.

In ORI Charge 3 it is alleged Respondent falsely reported by reusing and falsely labeling graphs to represent different things. ORI Ex. 67 at 26. In ORI Charge 3a it is alleged Respondent reused a graph to represent two different things. ORI Ex. 67 at 26. In ORI Charge 3b it is alleged Respondent reused a graph to represent four different things in two grant applications, five posters, and an article. ORI Ex. 67 at 27.

In ORI Charge 4 it is alleged Respondent falsely reported by reusing and falsely labeling western blot images to represent different things. ORI Ex. 67 at 28. In ORI Charge 4a it is alleged Respondent reused a western blot image to represent four different things. ORI Ex. 67 at 28. In ORI Charge 4b it is alleged Respondent reused a western blot image to represent three different things. ORI Ex. 67 at 30-31. In ORI Charge 4c it is alleged Respondent reused a western blot image to represent one different thing. ORI Ex. 67 at 32. In ORI Charge 4d it is alleged Respondent reused a western blot image to represent one different thing. ORI Ex. 67 at 34.

In ORI Charge 5 it is alleged that Respondent falsely reported by reusing and falsely labeling an image to represent one different thing. ORI Ex. 67 at 35.

Although not expressly stated in the individual charges, the false reporting alleged in all cases is the false reporting of PHS supported research.²⁵ To establish jurisdiction for itself and for me, ORI must establish a nexus between PHS support or a request for PHS support and the alleged research misconduct. 42 C.F.R. §§ 93.100-93.102, 93.221. ORI specifically alleges research misconduct in connection with PHS funded NIH grant applications, six unfunded and one funded. Applications or proposals for PHS supported research, research training or activities related to that research or research training; PHS supported research; PHS supported research training programs; PHS supported activities related to research or research training; and plagiarism of research records of PHS supported research, training, or related activities, are all covered by 42 C.F.R. pt. 93 and subject to charges of research misconduct. Although the nexus between PHS funding and the three publications, five posters, and one book alleged to contain false images in this case may not be clearly alleged by ORI, Respondent does not dispute that the necessary nexus exists to subject the use of false images and graphs in those materials to charges of research misconduct and administrative actions. I find it is undisputed that the materials published in the three publications, five posters, and one book were derivative of PHS supported research or purported to report the results of PHS funded research. ORI Ex. 67 at 5-8. Accordingly, jurisdiction for all the ORI charges exists.

ORI Charges 1, 2, 3, 4, and 5 each allege that Respondent actually did the false relabeling of images or graphs. The subordinate ORI Charges 1a, 1b, 1c, 1d, 2a, 2b, 3a, 3b, 4a, 4b, 4c, and 4d allege that Respondent reused but not that he actually did any false labeling.

In its post-hearing briefs ORI argues that Respondent “reused images and falsely reported them over and over again to show different experimental conditions.” ORI Br. at 1; ORI Reply at 1. ORI argues that Runko, the ORI Scientist-Investigator, determined that images were reused and falsely labeled. I note that reusing images does not constitute research misconduct under 42 C.F.R. § 93.103, unless alleged to be plagiarism. But there is no allegation of plagiarism in the charge letter. ORI Ex. 67. According to ORI, “[Respondent’s] conduct met the definition of falsification, because the reuse consisted of manipulating research materials or changing or omitting data or results such that the research is not accurately represented in the research record.” ORI Br. at 2. The ORI position is that even if Respondent did not create the falsely labeled or described images and graphs Respondent used them in grant applications, posters, articles, and a book. ORI Br. at 12-13; ORI Reply at 3. ORI is consistent in its briefs that Respondent committed research misconduct by falsely reporting PHS supported research by using the

²⁵ Adequate notice to Respondent is important. But Respondent has not objected on grounds that he did not have adequate notice due to the ORI omission of this important element in its charges; and because this is a civil administrative matter, not a criminal prosecution, the ORI omission requires no remedy.

same images and graphs that bore different labels or descriptions or using falsely described images or graphs in grant applications. The evidence before me does not support a finding that Respondent engaged in fabrication by personally applying false labels or descriptions on images for reasons discussed in this decision. But, ORI need not prove that Respondent actually applied the labels or descriptions that caused false reporting of PHS supported research. All ORI needs to prove is that Respondent intentionally, knowingly, or recklessly used images or graphs that bore labels or descriptions in grant applications or that caused the report of PHS supported research to be false.

b. Summary of what ORI has failed to prove by a preponderance of the evidence.

Regarding all the charges, I conclude that ORI has failed to show by a preponderance of the evidence that:

- (1) Respondent falsely labeled any of the images or graphs. The ORI evidence is that images were retrieved from two or more of five computer hard drives seized from computers in Respondent's laboratory, at least one of which was in Respondent's office. However, the evidence shows that all the computers were accessible by any of the staff, including the one in Respondent's office. The computer of Rafols, another possible creator of the images, was not seized until August 2012 (ORI Ex. 69 at 22 ¶ 107), 17 months after the initial seizure of 5 hard drives on February 23, 2011 (ORI Ex. 70 at 2 ¶ 4). The ORI evidence does not clearly establish which computer was the source of the images or graphs alleged to have been falsified or which user of all the possible users may have done the false labeling or placed the false images or graphs on the computer hard drive on which the images and graphs were found. Respondent has not conceded that he created any of the images or their labels or descriptions that are the subject of the charges.
- (2) ORI failed to show that three of the posters alleged to have reported the false images were actually published or presented. Therefore, ORI has failed to establish that reporting using those posters actually occurred.
- (3) ORI failed to show that Respondent intentionally or knowingly used any of the images which he now admits were falsely labeled or described.
- (4) ORI failed to show by a preponderance of the evidence which, if any, of the labels or descriptions for the various images or graphs were correct. ORI alleges that there are a total of 64 instances of the use of falsely labeled or described images and graphs in the 7 PHS grant applications, 3 publications, 5 posters, and 1 book. The images and graphs are described as portraying or depicting:

- Fluoro-Jade (FJ) labeling of neurons (ORI Charges 1, 1a, 1b, 1c, 1d);
- Systolic blood pressure curves (ORI Charges 2, 2a, 2b);
- Cerebral blood flow measurements (ORI Charges 3, 3a, 3b);
- Western blots (ORI Charges 4, 4a, 4b, 4c, 4d); and
- Immunofluorescent labeling of lectin (ORI Charge 5).

67 at 1. The specific ORI allegations of the false mislabeling of the various images and graphs are described in the discussion of the specific charges. In general, ORI alleges in most of the charges that there was a source image or graph that was correctly labeled and that Respondent used the same image or graph with a different label in grant applications, articles, posters, and a book. In order to establish the actual correct labeling for each of the images and graphs, it would have been necessary for ORI to present some expert testimony by experts with appropriate qualifications to establish the correct labeling and that any other labeling was incorrect. ORI did not present such experts, and I have no basis for crediting Runko with such expertise due to ORI's failure to establish his credentials. The ORI approach invites arguments by Respondent that some of the alleged false labeling of images and graphs may have actually been the correct labeling or that the difference in labeling may not have reflected any significant or material difference.

ORI invites me to infer that because an image file found on one of the computer hard drives seized from Respondent's laboratory had a date prior to the date of the grant application, article, book, or poster in which the image was reported, the image from the computer must be the original and correctly labeled or described image or graph. Runko does not explain how he determined the date of creation or alteration of the images and graphs that appeared in the grant applications, articles, posters, and book. Runko's analysis (ORI Ex. 19) and declaration (ORI Ex. 69) lead me to conclude that he simply assumed that some versions of the images and graphs that were in the grant applications, articles, posters, and book were created earlier than others and he also assumed that those created earliest were most likely correct. Again I emphasize that I have no evidence that Runko had any expertise related to the subject of any of the images or graphs.

The evidence shows that the images and graphs could have originated from as many as five different computer hard drives that were seized from the laboratory or from the hard drive from Rafols' computer which was not seized until 17 months later. The evidence does not appear to include a complete inventory of what Runko found on each of the five computer hard drives or Rafols' computer. ORI's charge letter shows that most of the images were found in multiple grant applications, posters, articles, and a book, and it is simply not possible on the current record to decide the original source of the reported images or graphs on the evidentiary record before me. However, when, for example, the same image has

multiple different labels, I may infer that it is more likely than not that at least one of the labels must be false. The inference is supported when, as in this case, Respondent actually identifies the falsely labeled images.

(5) In all the ORI Charges it is alleged that Respondent acted intentionally, knowingly, or recklessly. On their face, the ORI charges do not reveal the exact ORI theory on Respondent's state of mind. In post-hearing briefing ORI argues that the email evidence ORI introduced shows that Respondent acted knowingly or intentionally. ORI Br. 13-18, 22-23; ORI Reply at 9-18. ORI argues that the emails are the smoking gun that show that Respondent had a role in labeling or selecting images, citing ORI Exs. 23-25, 27, 30, 40-41, 68. ORI Br. at 13-14; ORI Reply at 10. I disagree that the emails show that Respondent acted knowingly or intentionally in using false images or graphs or that he labeled any images or graphs. The emails show that Respondent collaborated with others in drafting grant applications and an article, but they do not show that it was more likely than not that Respondent actually falsely labeled any image or graph.

The email cited by ORI as evidence show that Respondent was involved in the grant and/or article referred to in the email that included some images I conclude were altered to convey false information about PHS supported research. However, the email do not support a finding that it was more likely than not that Respondent actually knew that any of the images in the grant or article were false. However, as discussed in more detail hereafter, the email is evidence that Respondent recklessly permitted false reporting of PHS funded research in the grants, articles, and posters referred to in the charges.

c. What remains for ORI to prove?

In light of the foregoing findings, conclusions, and discussion, it is necessary to review the four elements ORI must prove in this case by a preponderance of the evidence in order to hold Respondent liable for research misconduct. ORI must show as to each charge that:

(1) Respondent used or intended to use false materials, in this case falsely labeled or described images or graphs, and that the materials were in fact false.

ORI must show that it is more likely than not that there was a "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results." 42 C.F.R. § 93.103. The regulations only apply when PHS support is involved, including applications or proposals for PHS support, PHS supported research, PHS supported research training, the dissemination of PHS supported research information, and plagiarism of records produced in the course PHS supported research. 42 C.F.R. § 93.102.

Fabrication is defined as “making up data or results and recording or reporting them. 42 C.F.R. § 93.103(a). Falsification is defined as “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.” 42 C.F.R. § 93.103(b). Plagiarism is defined as “appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.” 42 C.F.R. § 93.103(c).

The evidence in this case does not support a finding by a preponderance of the evidence that either fabrication or plagiarism occurred. The issue is whether Respondent engaged in falsification in the reporting of PHS supported research or research for which PHS funding was requested by using images or graphs with false labels or descriptions in the grant applications, published articles, posters, or book.²⁶

(2) The false materials were used in applying for PHS funding or in reporting PHS funded research.

There is no dispute in this case that there is a nexus between the alleged research misconduct and the proposing (i.e. grant applications) or reporting (i.e. publications such as published articles, published books, or posters that are presented) of PHS supported research or research for which PHS support was requested.

There is also no dispute that the grant applications, the published articles, the book, and two of the posters constituted reporting of PHS supported research or research for which PHS support was requested. Whether or not three of the posters were ever presented or published is an issue to resolve, for if not, they do not constitute research misconduct with the scope of 42 C.F.R. pt. 93.

(3) Respondent’s use of false materials violated the standard practices for the PHS research community established by the Secretary in 42 C.F.R. pt. 93.

ORI is required to show that the conduct alleged to be research misconduct is a significant departure from accepted practices in the relevant research community. I have concluded as a matter of law that the overarching relevant research community is the community of researchers and institutions that apply for and/or

²⁶ The research record includes research proposals, oral presentations, and journal articles. 42 C.F.R. § 93.224.

receive PHS grants. Thus, ORI meets its burden to establish that a respondent to a research misconduct charge engaged in conduct that is a departure from accepted practices in the relevant research community if ORI shows that the conduct is a departure from practices required by 42 C.F.R. pt. 93 for researchers and institutions that apply for and receive PHS grants. Whether or not the departure is significant or not is both a question of law and fact. Absent a specific definition for significant, I conclude that a violation of a regulatory or statutory requirement for the conduct of the relevant research community is a significant departure as a matter of law under 42 C.F.R. pt. 93. Institutions and researchers who apply for or conduct research using PHS funds bear an “affirmative duty to protect PHS funds from misuse by ensuring the integrity of all PHS supported work,” which is a clear statement of a duty and standard for the PHS research community. 42 C.F.R. § 93.100. Whether or not there are other relevant accepted practices of relevant research communities that are subsets of the research community that apply for and/or receive PHS grants is largely a question of fact. Whether or not Respondent rebuts the CMS *prima facie* showing with evidence of another relevant research community with accepted practices that differ from practices acceptable under the regulations is also a question of fact that is resolved as discussed in the Analysis of each charge.

(4) Respondent intended to use the false materials, knowingly used the false materials, or used the false materials recklessly, i.e., without exercising proper care or caution or with disregard or indifference to the risk that the materials were false. As discussed above, I conclude that ORI must show by a preponderance of the evidence, that a respondent to a research misconduct charge:

- Intended to use false, fabricated, or plagiarized materials, whether or not he or she accomplished the use of such material; or
- Used false, fabricated, or plagiarized materials knowing that they were false, fabricated, or plagiarized; or
- Used materials without exercising proper care or caution and disregarding or indifferent to the risk that the materials were false, fabricated or plagiarized.

ORI is required to show scienter or the required state of mind. But, I have found no statutory or regulatory requirement for ORI to establish that Respondent had the specific intent to defraud or mislead. I conclude that ORI did not show that Respondent intentionally or knowingly committed research misconduct in this case. However, the record shows that Respondent acted recklessly and committed research misconduct.

If ORI succeeds at proving the foregoing elements, Respondent has the burden to establish by a preponderance of the evidence any affirmative defenses, including honest error or difference of opinion, and any mitigating factors relevant to administrative actions based on a finding of research misconduct. 42 C.F.R. §§ 93.106(b)(2) and (3), 93.516(b)(2) and (3). However, the drafters, citing *Martin v. Ohio*, 480 U.S. 228, also provide that credible admissible evidence respondent submits to prove honest error or difference of opinion must be considered when deciding whether or not ORI or the institution meets its burden of proving by a preponderance of the evidence that research misconduct was committed intentionally, knowingly, or recklessly. 70 Fed. Reg. at 28,372, 28,378. I have considered Respondent's evidence as intended by the drafters when deciding whether ORI meets its burden. I note, however, that contrary to the suggestion of Respondent, ORI need not "exclude 'honest error.'" R. Br. at 4, 11. Respondent has the burden to establish honest error as a defense by a preponderance of the evidence, though evidence of honest error may be considered as negating the scienter element of the ORI prima facie case.

d. ORI's key witnesses, Runko and Cunningham

ORI relies heavily upon the testimony and declarations of Runko (ORI Ex. 69) and Cunningham (ORI Ex. 70) and Runko's image analysis (ORI Ex. 19). This evidence requires careful analysis when determining its weight and probative value.

Cunningham was called by ORI to testify. Cunningham identified his declaration admitted as ORI Ex. 70. Tr. 103-04. ORI called Cunningham, in part, to describe the process followed in sequestering computer hard drives and notebooks from Respondent's laboratory. Cunningham agreed on cross-examination that he was not involved in the actual sequestration of the five computer hard drives and he was not present when the hard drives were sequestered. He admitted that he was not involved in making the copies or images of the hard drives. He admitted that he had no personal knowledge about the hard drives or from which computers they were taken. He agreed that while he was present when the copies of the hard drives were packaged for shipping and shipped to ORI, he was not present when the hard drives were acquired or copied. He admitted that he was not present when the WSU Research Integrity Officer sequestered ten laboratory notebooks from Respondent's laboratory. He was also not present when the hard drive from Rafols' computer was sequestered and copied in August 2012. Cunningham also agreed that in his declaration he identified Rafols' and Respondent's office as being the same room – Room 9312 in Scott Hall – and he agreed that was an inconsistency. Tr. 170-76. On redirect examination, Cunningham stated that he reviewed the lists of materials that were shipped to ORI with the individuals that were responsible to ensure that the items were "assembled and packaged up and shipped." Tr. 192. Cunningham did not explain the handling of Rafols' computer in August 2012. In his declaration, Cunningham did not assert that he was involved with the sequestration of the computer hard drives and notebooks alleged to be from Respondent's laboratory. Rather, he

attested that he was “familiar with WSU’s sequestration policies and practices and with the sequestration of the computers and laboratory notebooks related to the research misconduct” investigation of Respondent. ORI Ex. 70 at 1. Cunningham states in his declaration that on February 23, 2011, the WSU Research Integrity Officer sequestered five hard drives from the laboratory and offices of Respondent. He states the hard drives were copied by the information technology (IT) office of the Vice President for Research. ORI Ex. 70 at 2 ¶ 4; Tr. 170-76. The record before me includes no testimony, declaration, or affidavit from the WSU Research Integrity Officer or anyone from the WSU IT office involved in the actual sequestration of the computer hard drives and notebooks or the copying of the computer hard drives. Without testimony of those who seized and copied the evidence, there is no evidence that a chain of custody was established or maintained for either the hard drives or the notebooks to ensure that what was received and examined by ORI was what was actually seized from Respondent’s laboratory.

There is also no evidence that the copies provided to ORI included the complete contents of the hard drives copied. Cunningham was admittedly not involved in sequestering the hard drives and notebooks and he cannot credibly testify as to how the hard drives and notebooks were seized or from where except based upon his conversations with third parties who were not present to testify at hearing. Cunningham does not reveal in either his testimony or his declaration the identities of the persons that executed the seizures of the original five hard drives in February 2011 or Rafols’ computer hard drive in August 2012, and there is no indication that he actually spoke with them. Cunningham cannot testify credibly that the hard drives and notebooks were seized from the correct rooms or specific machines. However, the break in the chain of custody does not defeat the ORI case because as discussed hereafter the evidence otherwise establishes Respondent’s connection to the allegedly falsified research materials, without the need to establish that materials ultimately reviewed or analyzed by Runko came from computers and notebooks from Respondent’s laboratory. Because it is not possible without a proper chain of custody and the testimony of those who seized and copied hard drives and notebooks, the weight of Runko’s analysis and testimony is reduced as it is not possible to ensure that he received and examined the correctly identified evidence.

According to Cunningham, based on information from unspecified persons, five computer hard drives were seized from more than three rooms associated with Respondent. One hard drive was taken from Room 9312 in Scott Hall, which Cunningham refers to as Respondent’s office, but in testimony Cunningham agreed that he also inconsistently identified Room 9312 as Rafols’ office (Tr. 175-76); one hard drive (referred to as “DXN861 Kreipke Old Machine”) was taken from a computer in a common area in Room 9332, Scott Hall; the laptop was found in Room 9316, Scott Hall which Cunningham characterized as a common room used by all members of Respondent’s laboratory. The other two hard drives were seized from other unspecified rooms that Cunningham characterized as “laboratory rooms or offices of the

Respondent.” ORI Ex. 70 at 2 ¶ 4. Given his testimony at hearing, I cannot rely upon the testimony or declaration of Cunningham as correctly identifying which office was Respondent’s and which was Rafols’ or which computer was in Respondent’s office. I received no floor plan of Respondent’s laboratory and have no clue as to how the rooms where the computers were located relate to each other. Cunningham also attests that on February 23, 2011, the hard drive from Reynolds’ (the Complainant) laptop was seized and copied, but he offers no details for how this laptop was identified as Reynolds’ computer, where it was found, or why it was still in the laboratory if it was Reynolds’ computer. ORI Ex. 70 at 2 ¶ 5.

According to Cunningham, the hard drive from Rafols’ computer was sequestered, also from Room 9312, Scott Hall, but not until August 8, 2012, 17 months after the first hard drive (characterized as Respondent’s) was seized from the same room. ORI Ex. 70 at 3 ¶ 7; Tr. 170-76. It is not clear from the evidence what activity was occurring in the laboratory during the 17 months between seizure of the initial 5 computer hard drives and Rafols’ computer hard drive and whether Rafols was present in the laboratory at the time of the seizure and how the computer was actually identified as being Rafols’. I also note, that by August 2012 when Rafols’ computer was sequestered the WSU Investigation had been completed for eight months. On December 1, 2011, the matter had been sent to Runko at ORI for action. Due to the fact that the WSU Investigation was completed and forwarded to Runko at ORI by December 1, 2011, it is more likely than not that Rafols’ computer was seized by WSU in August 2012 at the behest of ORI, possibly Runko. In his declaration, Runko makes no mention of the fact that ORI directed or requested the seizure of Rafols’ computer. Runko does state that he examined Rafols’ computer for the express purpose of determining whether Rafols shared culpability with Respondent for the falsifications, which supports my inference that ORI directed or requested the seizure of Rafols’ computer. ORI Ex. 69 at 22. The fact that ORI or Runko requested or directed the seizure of Rafols’ computer may seem to be a minor omission from Runko’s declaration and the ORI evidence. However, the omission of that fact clearly demonstrates that the ORI evidence may not be relied upon to give a clear or comprehensive view of the procedures followed. Further, it negatively impacts the weight of Runko’s declaration, analysis, and testimony, not because it suggests Runko is not truthful, but rather, it suggests that he may not be as thorough as one expects a trained investigator to be.

Although I find that Cunningham testified credibly to the extent he could recall, the fact that he did not participate in the actual seizure of the computer hard drives and notebooks, and that all his information is based on reports of unidentified third parties, means he cannot credibly attest to the location from which the hard drives and notebooks were seized or their correct identification. With that caveat, I note that Cunningham identified the hard drives sequestered as follows:

ASSIGNED IDENTIFIER (SOURCE OF THE IDENTIFIER NOT SPECIFIED)²⁷	TYPE EQUIPMENT FROM WHICH HARD DRIVE REMOVED	LOCATION FROM WHICH SEIZED
92XRPN1	TOWER COMPUTER	Rm. 9312 Scott Hall
DXN861	TOWER COMPUTER	Rm. 9332 Scott Hall
BFBTPL1	LAPTOP	Rm. 9316 Scott Hall
UNIDENTIFIED	UNSPECIFIED TOWER COMPUTER	Laboratory Rooms or Offices
UNIDENTIFIED	EXTERNAL HARD DRIVE	Laboratory Rooms or Offices
UNIDENTIFIED – REYNOLDS' COMPUTER HARD DRIVE	LAPTOP	Unidentified
UNIDENTIFIED – RAFOLS' COMPUTER HARD DRIVE	DESKTOP	Rm. 9312 Scott Hall

ORI Ex. 70 at 2-3 ¶¶ 4-5, 7.

Cunningham attests that ten laboratory notebooks were sequestered on February 23, 2011, by the WSU Research Integrity Officer from the common room, Room 9316 Scott Hall. ORI Ex. 70 at 2-3 ¶ 6. Cunningham was not present during the seizure and his testimony is based on reports from unidentified third parties. Cunningham identified the following ten laboratory notebooks as being seized:

LABEL ON FRONT AND SPINE	LOCATION WHERE SEIZED
SHAFFER 2008 BQ-123 BEHAVIOR	Rm. 9316 Scott Hall
BEHAVIOR 2010 ET-1 ICV BEHAVIOR	Rm. 9316 Scott Hall
CLAZOSENTAN BEHAVIOR	Rm. 9316 Scott Hall

²⁷ It would have been helpful to have property records from WSU or the owner of the automation equipment (computers and external drive) that showed serial numbers and to whom the equipment was assigned. The hard drive serial numbers could then have been correlated to the computers from which they were taken. More helpful would have been to have Respondent or another knowledgeable person present during the seizure so he could identify which computers were used by Respondent and which were used by laboratory staff.

SURGERIES 2009	Rm. 9316 Scott Hall
BEHAVIOR 2009/2010 (2ME2/E+RA ⁻ + B ⁻)	Rm. 9316 Scott Hall
2004 KREIPKE & P. SHAFER	Rm. 9316 Scott Hall
MORGAN 2005	Rm. 9316 Scott Hall
B. ATKINSON	Rm. 9316 Scott Hall
2009 WESTERN 50% BLANK	Rm. 9316 Scott Hall
B-APP EXPERIMENTAL PROTOCOL 98% BLANK	Rm. 9316 Scott Hall

ORI Ex. 70 at 2-3 ¶ 6. The evidence does not reflect whether copies or the originals were sent to ORI for examination by Runko. The content of the notebooks is not cited in the ORI charges.

Runko is characterized by ORI as a scientist-investigator who analyzed the images in question, examined the copies of the hard drives of five computers seized by WSU during its investigation, and, it appears from his declaration, drafted the ORI charge letter. ORI Ex. 69. However, as already noted, I have no evidence of Runko's qualifications to do the analysis he did for ORI. The title "scientist-investigator" has no meaning without some evidence of Runko's knowledge, education, training, experience, and skills.²⁸

²⁸ Fed. R. Evid. 702 and 703 provide excellent guidance for assessing whether one qualifies as an expert witness and how to weigh their opinions.

Rule 702. A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Rule 703. An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on

Runko was called to testify at hearing. He identified his declaration at ORI Ex. 69. But he did not testify to his qualifications as either a “scientist-investigator” or a witness with any particular expertise. Tr. 82-83. Runko states in his declaration that he was the ORI scientist-investigator, but the declaration also fails to identify any specific qualifications. ORI Ex. 69 ¶¶ 1, 7. On cross-examination he testified that he began working for ORI in November 2010 and he was assigned to the WSU Investigation in mid-2011, to provide information and technical assistance. Tr. 85-86. In response to my questions, Runko indicated that it was not his decision to charge Respondent and that decision is made in the Office of General Counsel (OGC). He testified that his role was providing his reports, exhibits, and analysis to OGC. However, he clarified that he did, in fact, recommend that Respondent be charged with research misconduct. Tr. 91-94.

Runko’s analysis and opinions are found in his declaration (ORI Ex. 69) and in his analyses of the various images and graphs (ORI Ex. 19) that are the bases for the ORI charges. ORI Ex. 69 at 12 ¶ 43. Runko’s image analysis is the basis, at least in part, of ORI’s charges and Runko’s findings and conclusions, as reflected in his declaration, are the evidence upon which ORI relies to support its charge letter and upon which ORI proceeds before me.

Runko states in his declaration that he used “EnCase forensic software to retrieve the images from the copies of the computer hard drives that WSU sequestered from Respondent’s laboratory rooms or office [and] used Adobe Photoshop to analyze the images.” ORI Ex. 69 at 7 ¶ 7. The evidence shows that WSU did not seize computers but rather the hard drives from various computers and an external drive and copies were sent to Runko. ORI Ex. 70 at 2-3; Tr. 170-76.

Runko purportedly used software to analyze each of the images at issue in this case and created an analysis of the image specifically for this case and, in his declaration and image analysis, he expressed many opinions about his observations. ORI Ex. 19; ORI Ex. 69 at 7, 12-13. I have no clue as to how Runko knew how to use any of the software he indicates he used, and I can have no level of confidence in the results he obtained absent evidence he actually had knowledge of and experience with the software.

the subject, they need not be admissible for the opinion to be admitted. But if the facts or data would otherwise be inadmissible, the proponent of the opinion may disclose them to the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect.

Except as noted hereafter, Runko generally did not use the identifiers used by WSU and Cunningham for the computer hard drives seized in February 2011. In his analysis (ORI Ex. 19 at 12-13 ¶¶ 43-56), Runko refers to “Respondent’s” computer without explaining how he determined which of the five copies of computer hard drives was from Respondent’s computer. In some cases, Runko provides no source for the image he analyzed. ORI Ex. 19 at 2, 6, 23, 25, 26, 34, 52, 56.

The computer identifiers used by WSU and Cunningham are also not used in the ORI Charges to identify on which computer hard drives images were found.

In his declaration, except in the case of some email files, Runko generally identifies figures or images as being taken from computers sequestered by WSU from Respondent’s laboratory rooms or office, but he fails to identify which specific hard drive or the single external drive was the source.²⁹ ORI Ex. 69 at 18-19 ¶¶ 88, 91, 106. In his declaration, Runko attests that he found the image in ORI Ex. 51 on two of the computers WSU sequestered, but he does not identify the computers. Runko states that the computer file was named “fig 3.tif” and it corresponds to “Figure 3 of the NR2011-1 publication” cited in ORI Charge 1a.” ORI Ex. 69 at 18-19 ¶ 88. In his analysis, Runko states that the file was created on Respondent’s computer on November 6, 2008, but he does not state how he identified the computer or the date the file was created. Runko identifies other images not specifically described in his declaration which he states in his analysis were created on Respondent’s computer on October 31, 2008, and he refers to those images as the source images. Runko does not tell us how he identified Respondent’s computer, how he determined the date of creation or how he determined an image was the source or exactly what that means. ORI Ex. 19 at 2, 6, 34. In his analysis, Runko identifies a graph purportedly depicting systolic blood pressures which he alleges was created on Respondent’s computer on May 23, 2008, but he does not state how he knows that or identify how he knew it was Respondent’s computer. ORI Ex. 19 at 52,

²⁹ The WSU Investigation report also refers to Respondent’s computer without specifically identifying which computer hard drive was the source of the various images and materials the WSU Investigation found incriminating. This evidentiary oversight negatively impacts the credibility of the WSU Investigation’s findings of fact. One can only wonder why computers were seized from Respondent’s laboratory without a knowledgeable witness present who could have actually identified who were the primary users for the computers that were seized. Seized hard drives should have been more specifically identified with primary users on a chain of custody document to which Runko could have referred in conducting his analysis. Even with the lower standard applicable in this case, i.e., a preponderance of the evidence, basic investigative techniques should be used to ensure the reliability and quality, i.e., the probative value of the evidence.

56. Runko identifies in his declaration ORI Ex. 54 as a computer file he found on two computer hard drives sequestered from Respondent's laboratory or office, but he does not identify which computers. Runko states the image file was named "ETRA IMAGE CLEAN.tif" and corresponds to Figure 2 in the grant applications R01 NS064976-01A1 and R01 NS064976-01A2, for which Respondent was the PI, and which are covered by ORI Charges 4a and 4b. ORI Ex. 69 at 19 ¶ 91. In many cases in his analysis, Runko did not specifically state that an image was taken from a computer hard drive seized from Respondent's laboratory, and I infer that in those instances, he most likely captured the image analyzed from the publication, grant application, poster, or book he refers to in his analysis.

Runko attests that he examined the five computer hard drives seized by WSU in August 2011, to identify email messages, specifically files with the extensions .pst or .ost, which are Outlook™ files. He attests that he examined "non-.pst files as well." ORI Ex. 69 at 21 ¶ 106. Runko did not clarify whether in addition to examining .pst files he just examined the hard drives for .ost files or whether he also examined for other file types such as documents, pictures, spreadsheets, databases, audio, video, or any of the other file types typically found on computers in the 21st century. However, we know that he did identify two images labeled as "fig 3.tif" and "ETRA IMAGE CLEAN.tif" on two computer hard drives taken from Respondent's laboratory, but Runko did not specify which computers. ORI Ex. 69 at 18-19 ¶¶ 88, 91. He attests that he located two .pst files on the laptop computer identified as BFBTPL1, which he says was in the common area of the laboratory, which is consistent with the inventory Cunningham oversaw, which listed the laptop in the common room, Room 9316, Scott Hall. Runko stated in his declaration that he also found one .pst file on a computer in Respondent's office, specifically the computer designated as 92XRPN1, which was identified by Cunningham as being found in Room 9312 of Scott Hall. Runko does not explain how he determined that 92XRPN1 was actually in Respondent's office rather than Rafols' office as he, like Cunningham, was apparently not present at the seizure and likely knows little more than Cunningham about how the computers were seized and from which areas in the laboratory. Runko refers later to 92XRPN1 as "Respondent's computer" but without any explanation for how that computer was determined to be Respondent's other than the fact it was in an office Runko thought was identified as Respondent's office in Respondent's laboratory. ORI Ex. 69 at 21 ¶ 106. The chain of custody in this case is minimally adequate to establish that copies of five hard drives came from WSU and rooms within WSU that constituted the laboratory at WSU in which Respondent worked. But the chain of custody is clearly inadequate to establish ownership, who was the primary user, who created the files, or even the rooms or locations where most of the hard drives were found. Nevertheless, Runko, without any explanation, refers to the email in the sent items folder of the .pst file from computer 92XRPN1 as having been sent by Respondent and he alleges that they were sent "within the relevant time period for the false reporting of data." ORI Ex. 69 at 21-22 ¶ 106. Runko does not establish in his declaration any factual basis to support this inference and I find his opinion is simply unsupported and

therefore not entitled to any weight on this point. It is certainly common knowledge that there are ways to identify a personal email account, but it is also common knowledge that many email accounts can be accessed from any computer or smart device. Runko's failure to specifically document and testify as to how he identified an email folder as Respondent's and then jumped to the conclusion that the computer was primarily for Respondent's use is a basic investigative failure that causes me to further question Runko's qualifications as an investigator. Runko also asserts that he did not find any email in inboxes, drafts, or other folders on the hard drives seized by WSU. I find it incredible that all the hard drives contained no email messages in any inboxes. Runko does not specifically mention any examination of archived email, and he does not mention any type of files other than email – not even a draft of a grant application or article in a word processing program is noted to have been located – the exception being the two .tif (image) files mentioned above. One can only speculate about the source of files attached to email that ORI and Runko indicate were found in email taken from a computer that they identify as being Respondent's, even though it is not clear how they would know that Respondent was the user of that particular computer. ORI Ex. 69 at 21-22 ¶ 106.

According to the list of computer hard drives seized by WSU, one is from a laptop listed as being Reynolds'. Runko did not state in testimony or in his declaration whether or not anything was found on Reynolds' computer hard drive.

Runko also attests that he scanned Rafols' computer sequestered in August 2012, roughly 17 months after the five computer hard drives were sequestered in February 2011. Runko does not explain what he means by stating he scanned Rafols' computer. ORI Ex. 69 at 22 ¶ 107. It is not apparent from the evidence how Rafols' computer was identified as Rafols'. The evidence shows that the computer identified as Rafols' was also found in Room 9312 Scott Hall, the same room from which the computer hard drive identified as 92XRPN1 was seized. Again there is no evidence as to why 92XRPN1 was seized in February 2011 but the computer identified as Rafols' was not seized until 17 months later – months after completion of the WSU Investigation report and its transmission to ORI on December 1, 2011. I can only speculate why one was taken and the other not during the original seizure of computers.

Runko attests that on Rafols' computer hard drive, he found 670,912 computer files with dates from January 4, 1996 to August 9, 2012, and 10,402 email from September 10, 2003 to June 15, 2012. Runko's declaration and testimony do not show that he examined all the files on Rafols computer, only that he "scanned the computer files for image files or documents that contained images, graphs, tables, or figure for the falsified data in question." ORI Ex. 69 at 22 ¶ 107. I infer from Runko's testimony that because he found files on Rafols' computer with dates in June and August 2012, that someone had access to Rafols' computer after the seizure of the initial collection of computer hard drives in February 2011. This evidence also shows it was more likely than not that, if in

fact the computer was actually Rafols', he returned to WSU and was in rooms identified as Respondent's laboratory in 2012, or the computer was accessed by others. Runko attests that he found "three instances of draft grant application language" on Rafols' computer that contained the same false images that Runko determined were used in grant application R01NS039860-09A2, specifically Figures 3A, 3B, and 8B. Runko did not attest to the dates those files on Rafols' computer were last accessed, though those dates could have been significant. ORI Ex. 69 at 22 ¶¶ 107-108. Runko concluded, however, that it was Respondent, not Rafols, who was responsible for the three false images because he concluded that Respondent had provided versions of Figures 3A and 3B to Dore-Duffy and she included them in her grant application and Respondent provided Figure 8B to Rafols for use in R01 NS039860-09A2. Runko cited the sworn testimony of Dore-Duffy during the VA investigation of Respondent, in which she testified that images were sent to her by Respondent. ORI Ex. 69 at 22 ¶ 108. However, Dore-Duffy also testified that she had no idea whether Respondent, Rafols, or someone else in Respondent's laboratory actually performed the experiments or put together the figures Respondent provided her. She stated that Rafols "did a couple things," but she was not specific and whatever Rafols did was not clarified during her VA interview. ORI Ex. 66 at 19-21. Runko opines that Respondent provided Dore-Duffy with versions of Figures 3A and 3B. Assessing the credibility of Runko's opinion is challenging. Dore-Duffy was testifying as part of the VA investigation. Her testimony refers to documents that were apparently marked as exhibits to the VA investigation and related to VA grants. ORI placed the report of the VA investigation in evidence as ORI Ex. 58, but did not include the exhibits to the VA investigation report. In her testimony Dore-Duffy refers to various exhibits but, despite a thorough effort comparing exhibits before me to exhibit numbers to which Dore-Duffy refers in her testimony, I cannot correlate the exhibit numbers to which she refers to any of the exhibits before me.³⁰ I also find no reference in

³⁰ Analysis and weighing of the documentary evidence in this case is challenging due to the way the evidence was assembled and marked for my consideration. As already noted, the exhibits collected by the VA investigation (except the sworn statement of Dore-Duffy (ORI Ex. 66)) and WSU Investigation were not offered with the reports of those investigations, rendering the reports of the findings and conclusions of those investigations effectively useless to me except as evidence of the procedural history of this matter. The WSU Investigation report lists 70 exhibits which are cited extensively throughout the report. ORI Ex. 1 at 42-43. The VA investigation report refers to 127 exhibits. ORI Ex. 58 at 1. The ORI charge letter dated February 10, 2016 (ORI Ex. 67 at 1-4) and the document titled "The Office of Research Integrity's Findings of Research Misconduct Against Christian Kreipke (Charge document)" appended to the charge letter (ORI Ex. 67 at 5-39) were marked and admitted as ORI Ex. 67. None of the exhibits referred to in the Charge document were included with ORI Ex. 67 and ORI Ex. 67 does

her testimony to Figures 3A and 3B. Therefore, I cannot determine that Runko's opinion that Respondent provided Figures 3A and 3B to Dore-Duffy is credible because I cannot find evidence consistent with that opinion.

Runko does not share the ultimate disposition of the computer hard drives or copies of those drives seized in February 2011 or the computer hard drive identified as Rafols' that was seized in August 2012. ORI Ex. 69 at 7 ¶ 7. Most of Runko's statements in his declaration are conclusory without any real explanation of the work he did, for example, ORI Ex. 69 at 2-9 ¶¶ 4-25, or, as in the case of ORI Ex. 69 at 9-12, 13-21 ¶¶ 26-42, 57-105, statements that appear to be intended to authenticate various exhibits although with no foundation for how he knows the various documents are true and correct copies as he asserts. Runko states in his declaration that he performed image analyses of images related to the ORI charges, the results of which are in ORI Ex. 19. ORI Ex. 69 at 12-13 ¶¶ 43-56. But, Runko does not address in his declaration the procedures followed in conducting his image analyses.

In his declaration, Runko states that ORI Ex. 60 is a copy of the laboratory notebook Respondent brought to his ORI interview on August 6, 2012. He alleges that the notebook is pertinent to the aggravating factors listed in paragraph 184 of the Charge document (ORI Ex. 67). ORI Ex. 69 at 20 ¶ 97. The allegation in the Charge document is found in paragraph 184g and that allegation is that the notebook had been altered to reflect earlier dates than originally entered. Paragraph 184g of the Charge document alleges that a forensic ink and handwriting expert determined that dates had been altered to make them appear to be earlier dates. The forensic examiner's findings and opinions are contained in ORI Ex. 62 and have not been challenged by Respondent. I note that the alteration of this notebook is not alleged to be the basis for a charge of research misconduct. Runko does not state in his declaration that any of the seized notebooks

not include a list of the exhibits referred to by ORI in the Charge document. However, by comparing ORI Exs. 1 through 66 with references to the exhibits in the Charge document, I conclude that there is a direct correlation. For example ORI Ex. 1 is the WSU Investigation report; ORI Ex. 2 comprises pages from a grant application that correspond to the description of ORI C.L. Ex. 2 in footnote 1 of ORI Ex. 67 at 5; ORI Ex. 3 is a grant progress report that roughly meets the description (difference in the grant number appears to be a clerical error) of ORI C.L. Ex. 3, which is also cited in footnote 1 of ORI Ex. 67 at 5. I conclude that ORI Exs. 68 through 74 are documents placed in evidence by ORI that were not considered at the time of the preparation of the ORI Charge document. Government's Exhibit List and Witness List (DAB E-File #25); Government's List of Admitted Office of Research Integrity Exhibits (DAB E-File #58b), ORI Ex. 69 at 1-2 ¶ 3; Tr. 436.

listed in the table of seized laboratory notebooks above contained information pertinent to any of the charges of research misconduct.

It is worthy of note that Runko actually found draft manuscripts and grant application language on Rafols' computer hard drive seized in August 2012, but not on any of the five hard drives seized in February 2011. Runko concluded that Respondent was culpable but not Rafols, but he did so without addressing significant holes in the evidence and I find his opinions regarding culpability are not well supported by the evidence and entitled to no weight. ORI Ex. 69 at 22-23 ¶ 108. In my analysis, it is significant that Runko can point to no file that he can attribute as coming from a computer identified as even regularly used by Respondent and on which Respondent may have created or falsely labeled or falsely described an image used to report false PHS supported research or research for which PHS support was requested. The fact that Runko found email that contained text he believes showed Respondent's involvement with various articles and grants or with attachments that he concluded were falsified in some respect, does not establish that Respondent created or falsely labeled or described any images or graphs referred to or included in an enclosure to the email. While Respondent has never disputed sending the various email placed in evidence by ORI, he has also been consistent that he did not know that any material transmitted by email was false and that he did not create any of the falsely labeled images or described email.

I find credible Respondent's explanation to the WSU Investigation that he did not personally do experiments in the laboratory. He also stated that there was a problem in his laboratory because information related to various experiments conducted in the laboratory was maintained on personal laptops and WSU-issued computers. Data was transferred to his "personal computer" in his office as necessary, and staff generally were expected to keep the data themselves.³¹ Laboratory notebooks were scattered throughout the laboratory. Notebooks were related to experiments not personnel. Everyone that worked on an experiment could add to the notebook for that experiment. ORI Ex. 64 at 12-13. Respondent's admission that his laboratory was loosely managed is an admission that has an air of truth that is consistent with other evidence of record.

³¹ Although Respondent's interview responses were unsworn, the responses are nevertheless relevant and the statements of a party opponent are not hearsay. *See* Fed. R. Evid. 801(d)(2). Respondent did not object to my consideration of ORI Ex. 64 on grounds it was an unsworn statement or uncounseled (a union representative was present). Accordingly, I find it appropriate to consider Respondent's responses in ORI Ex. 64.

e. The specific charges

(1) ORI Charge 1: Respondent intentionally, knowingly, or recklessly falsified the reporting of Fluoro-Jade cellular labeling of neurons by re-using and falsely labeling images to represent different brain regions in animals subjected to different treatments – TBI, exercise, and/or administered with different endothelin receptor antagonists.

ORI alleges 17 charges, ORI Charges 1, 1a, 1b, 1c, 1d, 2, 2a, 2b, 3, 3a, 3b, 4, 4a, 4b, 4c, 4d, and 5. The numbering ORI chose is misleading in that it suggests five major charges, four of which have subordinate charges or, lesser included offenses. In fact, there is no superior and subordinate or primary and lesser charges involved but, rather 17 separate charges. The only relationship among the primary and subordinately numbered charges is the fact that they involve a similar image or graph. If there is some other relationship of significance ORI has failed to show the significance.³² I have already discussed my conclusion that ORI failed to show it is more likely than not that Respondent actually created any false images. In the interest of judicial economy, I find it unnecessary to

³² The significant point is that there are a total of 17 charges that Respondent must defend, most of which include multiple allegations of research misconduct. It would have been less confusing if ORI had simply numbered the charges 1 through 17. It would have been even better for purposes of analysis, hearing, and decision, if ORI, which alleges 64 separate instance of research misconduct, had set forth each as a separate charge. Many of the charges allege misconduct related to the same grant applications, manuscripts (articles), and posters but involve different figures (images or graphs) or panels within those documents. References to grant applications (whether or not they were ultimately approved by NIH) may be identified by the fact that all grant numbers are preceded by “R01.” All the articles and posters are identified by two alpha characters followed by four numerals. A more specific identification for each article and poster is provided in the table following each charge. There are references to manuscripts in the record. Manuscript may be confused with unpublished writings. In this case, there is no dispute that all the manuscripts referred to in the charges were actually published in journals and were, therefore, reported to the audiences of those journals. Therefore, the term “article” is used rather than “manuscript” to avoid the misconception that some of the articles referred to may not have been reported, raising the issue of whether they are a basis for a finding of research misconduct.

repeat under each of ORI Charges 1, 2, 3, and 4, my prior analysis for why ORI failed to show Respondent created any of the false labels or descriptions.

(2) Charge 1a: Respondent intentionally, knowingly, or recklessly re-used a single image of hippocampus, 48 hours post-TBI, no treatment, to represent

(a) *20 nmol anti-calponin antibody treatment in smCx*³³ in

R01 NS064976-01A1, Figure 8, and

R01 NS064976-01A2 and R01 NS039860-09A2, Figure 8B; and

(b) *clazosentan treatment in smCx* in

NR2011-1 Figure 3 and in the posters WB2009, VA2009, and VA2010, Figure 6, and WC2010, Figure 5.

ORI Ex. 67 at 16.³⁴

There is significance to the use of the italics in the charges as set forth in Runko's declaration and the ORI Charge document. The charges as they are set forth in Runko's declaration appear to be nearly identical to the way they are set forth in the Charge document.³⁵ However, careful examination reveals a distinct difference between Runko's allegations in his declaration and the allegations in the Charge document. In his declaration, Runko states that italics are used in the charges to denote the falsifications he found. ORI Ex. 69 at 3-7 ¶ 6. However, ORI states in the Charge document that "[d]ifferences in the labeling of the reused images from the original or earliest versions of the images are denoted in italics in the ORI findings." ORI Ex. 67 at 16 n.16. Thus, Runko states that the italicized information in the charge is the false description or

³³ In his declaration, Runko in ORI Issue 1a indicates the abbreviation is for sensory motor cortex. ORI Ex. 69 at 4. I infer that Runko is referring to the sensorimotor cortex.

³⁴ A list format is adopted with the objective of making it easier for the reader to understand the charge.

³⁵ I recognize that in the Charge document the charges are in bold typeface but they are not in Runko's declaration.

labeling of the image or graph, while ORI states in the Charge document that the italicized language is used merely to differentiate from an earlier description or label of an image. More specifically, Runko alleges that the italicized language is false while ORI does not specifically allege whether the italicized language was or was not false. Rather, ORI only asserts that the italicized language is different from that used in a prior description or label. Thus, I conclude that the ORI approach is not to allege that a specific image description or label is false but, rather, the allegation is that Respondent used two different labels for the same image and one must be false. ORI's approach is different in Charge 5 in which it is specifically alleged that Respondent falsified reporting of research results by falsely labeling an image. The italicized language in the charges as set forth in Runko's declaration and in the Charge document is retained in this decision. ORI's different approach in Charge 5 confirms my analysis that in the other charges ORI does not allege that one label is false and another is not, but that the use of two different labels establishes or permits the inference that one or the other of the labels or descriptions must be false.

Charge 1a, in simpler terms, is that Respondent used an image that was relabeled by some unspecified individual to reflect: (1) different treatment, i.e., either anti-calponin antibody or clazosentan, versus no treatment; and (2) different areas of the brain, i.e., hippocampus versus sensorimotor cortex. A glaring omission from ORI Charge 1a is the allegation that any of the labeling is actually false.³⁶

In this analysis I use the term "label" to refer to text, numbers, or symbols that appear on or overlay an image and the term "description" to refer to the text that accompanies an image. The term "image" is used to refer to a photographic image of a subject, unless otherwise stated. Graphs, charts, tables, and similar items are referred to specifically by type. Tr. 801-02.

For the reader's benefit, I note that the images in the grant proposals, article, and posters in ORI Charge 1 appear to be either green or white spots on a black background, akin to the appearance of stars on a very dark night. The spots are green in ORI Ex. 2 at 6, ORI

³⁶ ORI may have felt that it was sufficient to make that allegation in ORI Charge 1. The omission reflects why 64 separate charges, each capable of standing alone would have been better numbering technique for the ORI charges. Because this is not a criminal proceeding and Respondent has not specifically challenged the adequacy of ORI Charge 1a, I have determined not to simply reject this charge on grounds that it fails to allege research misconduct or a violation of the regulations. ORI Charge 1 does allege that Respondent falsely labeled images, which I conclude to be sufficient notice to Respondent of what to defend. However, ORI should be cautious to ensure its charges provide fair notice to respondents of that which they must defend.

Ex. 5 at 4, ORI Ex. 7 at 12, ORI Ex. 14, ORI Ex. 15, ORI Ex. 16, and ORI Ex. 17, and white in ORI Ex. 11 at 4. These images are meaningless to a layperson and anyone without the specific expertise necessary to identify and understand what the images represent. However, the differences and similarities among the various images and their labels or descriptions are readily discernible even to a layperson. Although the labeling and descriptions are different, a layperson can discern that the arrangement of the green or, in the case of ORI Ex. 11 at 4 white specks, are the same in all the images, supporting an inference that all the images originate from a common image or like images but have different labels or descriptions.

(a.) ORI has made a prima facie showing that there are false images in the materials cited in the ORI Charge.

The charge refers to three images: (1) one image labeled or described to be hippocampus, 48 hours after TBI with no treatment; (2) an image used in the three grant applications with a label or description representing that the image reflects the effect of anti-calponin antibody treatment in the sensorimotor cortex following TBI (each image includes two slides: the one on the left described to show TBI without anti-calponin and the right slide is represented to show TBI with anti-calponin antibody treatment); and (3) an image used in the article, and four posters, with a label or description representing that the image is clazosentan treatment in the sensorimotor cortex following TBI (each image includes two slides: the one on the left described to show TBI without clazosentan and the one on the right described as showing TBI and the administration of clazosentan).

The following table lists the various images from the charge, a description of the type of document in which the image appears as that affects what ORI must prove, and the citation to the ORI exhibit where the document and image may be found.

IMAGE	DOCUMENT DESCRIPTION	DATE OF DOCUMENT	ORI EXHIBIT
R01 NS064976-01A1, Fig. 8	Grant Application, Respondent PI	11/17/2008	ORI Ex. 7 at 12
R01 NS064976-01A2, Fig. 8B	Grant Application, Respondent PI	3/13/2009	ORI Ex. 2 at 6
R01 NS039860-09A2, Fig. 8B	Grant Application, Rafols PI	6/29/2009	ORI Ex. 5 at 4 ³⁷

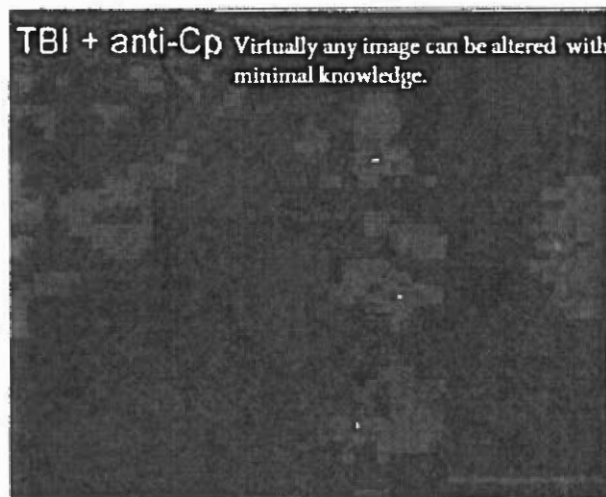
³⁷ The exhibit includes two different figures denoted 8B, one at ORI Ex. 5 at 4 and one at ORI Ex. 5 at 5. Charge 1a refers to the Fluoro-Jade image labeled “TBI + anti-Cp” at ORI Ex. 5 at 4 (right-side). Tr. 614-15.

NR2011-1, Fig. 3	Christian W. Kreipke et al., <i>Clazosentan, A Novel Endothelin A Antagonist, Improves Cerebral Blood Flow and Behavior After Traumatic Brain Injury</i> , 33 Neurological Research 208, 211 (2011)	2011	ORI Ex. 11 at 4
WB2009, Fig. 6	Winter Brain Poster	Undated	ORI Ex. 14
VA2009, Fig. 6	VA Presentation Poster	Undated	ORI Ex. 15
VA2010, Fig. 6	VA Presentation Poster	Undated	ORI Ex. 16
WC2010, Fig. 5	World Congress Poster	Undated	ORI Ex. 17

The charge alleges that Respondent re-used an image that represented a sample of hippocampus, 48 hours after TBI with no treatment, which for convenience I refer to as the source image. I am not satisfied that the source image has accurately been identified by ORI or that it is in evidence before me. It is significant that ORI has not presented evidence to establish that the correct label or description for the source image is “hippocampus, 48 hours after TBI with no treatment.” Neither Cunningham nor Runko actually testified or stated in their declarations that they knew the correct characterization for the source image, and I have no evidence that they were qualified to so opine. The so called “source image” is discussed in more detail hereafter.

Runko tells us in his declaration that pages 2 to 5 and 10 to 33 of ORI Ex. 19 accurately explain his image analysis related to ORI Charge 1a. ORI Ex. 69 at 13. But, Runko’s image analysis includes minimal or no narrative describing the procedures he used for any of his analysis or the basis for his conclusions and opinions. Runko’s analyses show that he made various changes to the images he analyzed. In the case of the source image for ORI Charge 1a, Runko’s manipulations of the image reflected in his analysis (ORI Ex. 19) revealed no more relevant substantive evidence than a layperson can discern with no manipulation of the image. The labeling, background and spot color, and the arrangement of the spots are readily apparent to the layperson. I find the analysis related to ORI Charge 1a neither enlightening nor helpful, and the same is true for the remainder of Runko’s analyses. The credibility of Runko’s analyses is impacted negatively by some unsupported opinions he asserts in ORI Ex. 19. The first example relates to the source image. Runko states that an image was found on “Respondent’s computer.” Runko does not identify from which of the five hard drives seized from Respondent’s laboratory and office rooms the image was extracted. Runko described the image file as named “FJ Hipp 20x 48h TBI.tif” and that it was created on October 31, 2008, on “Respondent’s computer.” Runko concluded that the image was “purportedly Fluoro-Jade (FJ) labeled rat hippocampus, 48 hours post-TBI.” ORI Ex. 19 at 2. But Runko does not state the

basis for his conclusion that the image he found was an image of a sample of rat hippocampus or that FJ stands for Fluoro-Jade staining, and I have no evidence that Runko had the expertise necessary for such an identification. Runko also does not opine whether the image actually portrayed Fluoro-Jade-stained rat hippocampus 48 hours post-TBI with no treatment, but I would find that there is no evidence that he had the expertise to credibly testify to such an opinion. Runko includes in his analysis an image composed of two slides, labeled “TBI_anti Cp.tif” which he states was created on November 6, 2008, on Respondent’s computer. Runko does not state from which of the five hard drives the image was extracted. Runko asserts that the image shows Fluoro-Jade labeled rat sensorimotor cortex, the slide on the left untreated and the slide on the right treated with anti-calponin antibody. ORI Ex. 19 at 2, 6. Runko also renders additional opinions that files he found on Respondent’s computer, from which of the five hard drives is also not specified, were used to create the images in the grants, articles, and posters. ORI Ex. 19 at 2-25, 30-33. Runko states no basis for his opinions, and I have no evidence that he has the necessary expertise. However, as a layperson, I can identify that the image that is the subject of Charge 1a is the same as the image that appears in ORI Exs. 2 at 6, 5 at 4, 7 at 12, and 11 at 4 (except for the color of the spots), and 14 through 17, but with different labels overlaying the image. Runko manipulates the slides in various ways all in obvious effort to support his opinions. Because there is no evidence that the images in ORI Exs. 2 at 6, 5 at 4, 7 at 12, and 11 at 4, and 14 through 17 contain labeling or metadata that permit determination of what computer created the images, Runko’s conclusion that those images had a common origin in Respondent’s computer, whichever computer hard drive that was, is not even an educated guess. Images can be captured from virtually any digital file and altered as confirmed by the articles introduced by ORI as ORI Exs. 71, 72. For example, I have taken the following image directly from Runko’s analysis (ORI Ex. 19 at 6 (lower-right slide)) and altered it with the commonly available Windows Snipping Tool™ and Adobe Acrobat™. There is no question it is the same image as analyzed by Runko but now with a different label from that which appears in ORI Exs. 2 at 6, 5 at 4, and 7 at 12, and from a different computer piloted by a Judge with little computer expertise.



I conclude that in addition to having little information regarding Runko's qualifications, his analysis is neither persuasive nor particularly helpful. Accordingly, I conclude that Runko's analysis of the images identified in ORI Charge 1a is entitled to little weight. This conclusion applies to Runko's entire analysis as it relates to all 17 charges.

Based on my own lay analysis I find that the underlying image is common to all the images in issue under ORI Charge 1a, whether from a single original image file or multiple different image files cannot be determined on the present record. Runko found similar images on copies of computer hard drives from Respondent's laboratory, but he does not tell us from which computer hard drives.

Runko's analysis also sheds no light on the very important issue of whether any of the labels in ORI Exs. 2 at 6, 5 at 4, 7 at 12, 11 at 4, and 14 through 17 are actually false.

The source of the images alleged to be false is not established by other ORI evidence. An image similar to that in the article (ORI Ex. 11 at 4) was attached to an email from Respondent to Donald Kuhn dated May 24, 2010. The image (ORI Ex. 23 at 4) is the same image as appears in the article (ORI Ex. 11 at 4) and Respondent says in the email that he is forwarding "the first of two manuscripts that will be published in Neurol Res." ORI Ex. 23 at 1. ORI Ex. 24 is an email from Respondent to "manueldujovny@hotmail.com" on May 24, 2010, with the same image attached as appears in ORI Ex. 11 at 4 and was also attached to the email to Kuhn (ORI Ex. 23 at 4). ORI Ex. 24 at 4. The same image was attached to an email from Respondent to William M. Armstead on May 19, 2010. ORI Ex. 25 at 4. Runko asserts that ORI Exs. 23, 24, and 25 are true and correct copies and that the figures attached to the emails are those that appear in ORI Ex. 11, but he fails to state the basis for his opinions. However, I can determine by simply comparing the draft articles and images attached to ORI Exs. 23, 24, and 25 and the published article (ORI Ex. 11) that the images at ORI Exs. 23 at 4, 24 at 4, and 25 at 4 are the same as the image at ORI Ex. 11 at 4. This evidence shows that Respondent had the image files and had the ability to send them by email. ORI Exs. 40 through 42 and 48 and 49 are also email from Respondent related to the article in ORI Ex. 11 but contain no images. Runko declares that ORI Exs. 40 through 42 and 48 and 49 are true and correct copies of email from Respondent but does not share how he knows that. He also asserts that these email show Respondent's role in editing the article (ORI Ex. 11). Respondent's role as the first listed author of the article is not really in issue. ORI Ex. 69 at 17-18 ¶¶ 77-79, 85-86. This evidence does not establish that any of the images, labeling of images, or descriptions of the images are false.

Runko states in his declaration that ORI Ex. 51 is a copy of an image he found on two computer drives seized from Respondent's laboratory rooms or office. He does not state which hard drives contained the image. ORI Ex. 69 at 18-19 ¶ 88. A layperson can

readily discern that the image in ORI Ex. 51 is the same as the image in the article (ORI Ex. 11 at 4).

As already noted, an important element of the ORI case is to establish its theory that the images, labels, or descriptions are actually false as portrayed in ORI Exs. 2 at 6, 5 at 4, 7 at 12, and 11 at 4, and 14 through 17. Runko does not render a credible opinion that any of the labeling is false and the evidence does not show he has the expertise necessary to render such an opinion. ORI Exs. 19, 69. Cunningham did not render the opinion that any of the images as labeled or described are false, and I have no evidence that he was competent to do so. ORI did not present any expert opinion as to whether any of the labels on the images under examination were actually false. Unfortunately, the judge is not qualified to make that determination based on the present record. However, not all is lost for ORI on this charge if Respondent admits that any of the images, their labeling, or descriptions are false.

ORI Ex. 68 is an email thread from Respondent to Rafols on February 28, 2011 and from Rafols to Respondent on March 2, 2011. Respondent states that figure 3 in the article (ORI Ex. 11 at 4) is the “incorrect figure for Clazosentan treatment.” Respondent clearly does not admit that figure 3 in the image at ORI Ex. 11 at 4 is false, fabricated, or plagiarized.

ORI Ex. 74, the notice of retraction of the article in ORI Ex. 11 and others, states that the WSU Investigation found images in the articles were used in other instances to represent different results and that the data “were fundamentally unreliable.” However, the notice of retractions does not state that any image label or description was determined to be false.

On July 8, 2011, the WSU Investigation received the unsworn³⁸ statement of Steven Schafer, who began working in the laboratory with Respondent and Rafols as a laboratory assistant in 2008. ORI Ex. 65 at 4-6. Schafer stated that he was involved with using both clazosentan and BQ-123 in the laboratory, probably in 2009. ORI Ex. 65 at 18-20. Schaefer stated that Fluoro-Jade staining was used with both clazosentan and BQ-123. ORI Ex. 65 at 26. He stated that he took photographs of Fluor-Jade stained rat brain tissue which he gave to Respondent on a flash drive, but he stated he did not know what Respondent did with the images. ORI Ex. 65 at 28-29. During the interview, Schafer was shown a figure with four panels: the top two panels were described as “TBI and TBI plus Clazo and the bottom one [was] labeled TBI and TBI plus Anti-C.” ORI

³⁸ The fact the statement was unsworn means that the person interviewed was not advised of the obligation to tell the truth, the source of such an obligation, or any possible sanction for not telling the truth.

Ex. 65 at 59. Schafer was told they were from two different sources and he was told that even a nonscientist could tell the figures were identical but labeled differently. Schafer identified the images as a Fluoro-Jade stain picture. Schafer stated he had no idea how it happened that using two different therapeutic agents would result in the same image. Schafer was not asked if he could identify the images as having come from Respondent's laboratory or whether the images he looked at were false. ORI Ex. 65 at 59-60. The interviewers did not refer to any exhibit or other marking of the images to which they referred, whether they were in hard copy or projected, and I cannot correlate their vague references to the images in ORI Exs. 2 at 6, 5 at 4, 7 at 12, and 11 at 4, and 14 through 17.

In the Charge document (ORI Ex. 67 at 16 ¶ 27), which appears to have been largely drafted by Runko (ORI Ex. 69 at 7-8 ¶¶ 8-20), it is alleged that Respondent told the WSU Investigation that an image represented Fluoro-Jade labeling of samples of hippocampus at 48 hours post-TBI with no treatment, at 20 times resolution, citing sections of the transcript of Respondent's unsworn interview by the WSU Investigation (citing ORI Ex. 64 at 25-33, 70-72, 80-81). ORI Ex. 67 at 16 ¶ 27. The drafter of ORI Charge 1a suggests that Respondent identified the image he viewed during his interview by the WSU Investigation as the source image in ORI Charge 1a, but that assertion is incorrect. I find that inference is simply not supported by the evidence.

During the WSU Investigation interview by Cunningham and others, Respondent was shown various projected images (slides – ORI Ex. 64 at 3-4) in a PowerPoint™ presentation assembled by Cunningham. The slides were shown to Respondent without reference to a name, exhibit or figure number, or specific description of the image and Respondent was asked to comment about the slide or image. Because the images Respondent was shown were not identified by some marking or other identification, it is extremely difficult and in most instances impossible to determine to what Respondent's comments actually related because it is not clear exactly what image Respondent was being shown.³⁹ Cunningham asked Respondent questions about WSU allegation 1. ORI Ex. 64 at 17. The WSU allegations are different from the ORI charges. ORI Ex. 1 at 3-4. However, WSU allegation 1 related to Respondent's grant (it is unclear which grant was referred to – ORI Ex. 7 at 12 or ORI Ex. 2 at 6) and the article (ORI Ex. 11 at 4). WSU allegation 1 alleged that the image in the grant showed the effect of anti-calponin antibody while the image in the article represented treatment with clazosentan. ORI Ex. 1 at 3. Although not specifically stated in the transcript of the interview, it appears that Respondent was shown the images from the grant and the paper side-by-side. It was

³⁹ Many times during the interview the interviewers seemed more interested in debating theory and criticizing Respondent's methods (e.g., ORI Ex. 64 at 41-44) than actually exploring what Respondent knew and did or did not do.

asserted by Cunningham that the images were identical, but one was labeled “clazo” and one labeled “anticalponin.” ORI Ex. 64 at 17. Respondent was also shown posters or images of posters “where the same figure is present.” ORI Ex. 64 at 17-18. It is not clear that the posters Respondent was shown are the posters referred to in ORI Charge 1a and found in ORI Exs. 14 through 17. Cunningham asked Respondent which figure was correct. Respondent told Cunningham that Reynolds picked the figures for the article (ORI Ex. 11) and he put the wrong figure in the manuscript. Respondent stated that the error was not discovered in editing and it was not discovered until the complaint of research misconduct. The error was reported to the journal and the correction was made. ORI Ex. 64 at 17-19. Respondent told the WSU Investigation that “the correct figure here is anticalponin, okay?” ORI Ex. 64 at 20. Of course, the transcript does not show what figure Respondent was seeing or referring to. Respondent was shown an image that Cunningham represented was taken from Respondent’s computer which Respondent identified as Fluoro-Jade in the hippocampus at 20 times resolution at 46⁴⁰ hours post-traumatic brain injury. The image Respondent was viewing is not identified or further described in the transcript. ORI Ex. 64 at 25. The interview continued as follows:

DR. CUNNINGHAM: Here is that slide. Okay? If we open that slide, and then it’s dated 2008, if we then do an auto correction using just a standard image correction, and then increase the contrast, and we flip it. This is one of the images from all of those different documents I showed you. And here’s that image that you said was perfused with saline.

Now in all of your papers, it’s either clazo or calponin, but in your original image it appears to be neither one by the label.

Can you tell us how that happened?

DR. KREIPKE: I personally can’t speak to that, because again I don’t personally render the images.

DR. CUNNINGHAM: So this suggests that this image is actually wrong in every single publication; is that correct? Because you told us this is not treated with any - - with clazosentan or calponin right?

⁴⁰ ORI Charge 1a refers to 48 hours post-TBI so it is not clear if there was an error in the transcript or whether Respondent was looking at the name for some image file not related to ORI Charge 1a.

DR. KRIEPKE: And again I can't speak to if there is - - in this particular case, I can't speak to if there's an error in the labeling.

ORI Ex. 64 at 27-28.

The WSU investigators continued to interrogate Respondent referring to images that were never specifically identified and Respondent continued to deftly dodge direct answers. Respondent is subsequently shown an image which he states represented anti-calponin treatment but whether this is the image he previously identified as being anti-calponin treatment is never clarified by the examiners. ORI Ex. 64 at 32-33.

The interview continued:

DR. CUNNINGHAM: So here - - just some questions now. So I think we just answered this.

So from the label on what appears to be the original tif file, the micrograph should have been from the hippocampus of a TBI damaged animal with no therapeutic treatment. If that's so, then all of these images in your grants, publications and presentations are misrepresented. Can you provide evidence to the contrary?

* * * *

DR. KRIEPKE: The direct answer to that question is no.

ORI Ex. 64 at 39. This exchange is of particular concern for two reasons: (1) it shows Cunningham did not understand that the burden of proof was upon the institution and ORI and not Respondent under 42 C.F.R. pt. 93; and (2) Cunningham refers to images being "misrepresented" when the necessary element for research misconduct is that there be a falsification, fabrication, or plagiarism, not a misrepresentation.

After spending considerable time attempting to decipher Respondent's unsworn statement taken by the WSU Investigation (ORI Ex. 64), I conclude it is of little value as substantive evidence. Questions of the interviewers are not clear, references to potentially substantive evidence are not clear, and Respondent's responses are without context and are either evasive or reflect confusion about the question posed.

According to Charge 1a, there was a "source image" of a tissue sample from the hippocampus area of a rat brain stained with Fluoro-Jade following a TBI with no treatment. The evidence does not show that it is more likely than not that there was a

source image with such labeling. The charge alleges that the source image was relabeled, which is also not shown by the evidence to be more likely true than not. The evidence does show multiple like images as previously described based on my own observations. The images do appear in the various grants, the article, and the posters as alleged in ORI Charge 1a, labeled or described as samples from the sensorimotor cortex, post-TBI, with either treatment with “anti-calponin antibody” or “clazosentan treatment.” ORI did not offer any qualified expert opinion that the images as labeled in the grants, the article, or the posters were actually false. ORI has proceeded upon the theory that there was a source image that shows the Fluoro-Jade stained sample of rat hippocampus, 48 hours after TBI with no treatment, and that the other images were labeled or described differently and, therefore, they must have been false. ORI has failed to prove a source image, and I cannot draw the inference ORI invites. However, based on my lay observations, I have discovered that the same image appears in ORI Exs. 2 at 6, 5 at 4, 7 at 12, and 11 at 4, and 14 through 17, but with two different sets of descriptions or labels, i.e., the images in ORI Exs. 2 at 6; 5 at 4; and 7 at 12 are labeled and described as showing anti-calponin antibody therapy, and the images in ORI Exs. 11 at 4, and 14 through 17 are labeled and described as showing treatment with clazosentan.

While I certainly do not have the expertise to determine which label or description may be false, I may draw the inference that one set of labels is more likely than not false. Based on the inference that some of the labels are more likely false than not, I conclude that ORI has made a prima facie showing that at least some of the images referred to in the grant applications, the article, and the posters were falsely labeled. ORI Exs. 2 at 6, 5 at 4, 7 at 12, and 11 at 4, and 14 through 17. Respondent confirmed during my questioning at hearing that my inference is correct. Furthermore, Respondent forthrightly stated that the images labeled as clazosentan treatment referred to in ORI Charge 1a are incorrect. Tr. 795.

I conclude that the labeling of the images listed in ORI Charge 1a as being in grant applications R01 NS064976-01A1, Fig. 8; R01 NS064976-01A2, Fig. 8B; R01 NS039860-09A2, Fig. 8B are not more likely than not false. The images in NR2011-1 Fig. 3; WB2009, Fig. 6; VA2009, Fig. 6; VA2010, Fig. 6; and WC2010, Fig. 5 (ORI Exs. 2 at 6, 5 at 4, 7 at 12, and 11 at 4, and 14 through 17) are more likely than not falsely labeled as clazosentan treatment. The documents in which these false images are found, are either applications for PHS grant funds or constitute purported results of PHS funded research.

The next issue is whether Respondent intentionally, knowingly, or recklessly used the falsely labeled images.

(b.) ORI has made a prima facie showing that some of the materials cited in the ORI Charge were used in applying for PHS funding or in reporting PHS funded research.

The Secretary has delegated to ORI by regulation the authority to prosecute research misconduct. The regulatory delegation of authority applies specifically to applications or proposals for PHS support of research, research training or related activities, whether or not a grant was actually awarded; and any research proposed, performed, reviewed, or reported, or any research record generated. 42 C.F.R. § 93.102(b). Research misconduct for which administrative actions are authorized are the intentional, knowing, or reckless use (42 C.F.R. § 93.104(b)) of false, fabricated, or plagiarized materials “in proposing, performing, or reviewing research, or in reporting research results” (42 C.F.R. § 93.103). The charges in this case, referring to all the charges, do not allege the use of false images or other materials in the context of performing or reviewing research.⁴¹ Therefore, based on the ORI charges, ORI must show by a preponderance of the evidence that:

Respondent intentionally, knowingly, or recklessly used false images or other false materials in proposing research for PHS funding, i.e. grant applications whether granted or not; or

Respondent intentionally, knowingly, or recklessly used false images or other false material in reporting the results of research, funded or otherwise supported by PHS, in this case through the published articles or posters as alleged.

There is no dispute that the three grant applications listed in ORI Charge 1a were submitted to NIH for PHS funding. There is also no dispute that the article cited in ORI Charge 1a was actually published with the effect of reporting PHS funded research.

ORI also alleges in ORI Charge 1a that Respondent committed research misconduct based on the presence of falsely labeled or described images in four posters. The posters are WB2009 Figure 6, Winter Brain Poster (ORI Ex. 14); VA2009 Figure 6, VA Presentation Poster (ORI Ex. 15); VA2010 Figure 6, VA Presentation Poster (ORI Ex. 16); and WC2010 Figure 5, World Congress Poster (ORI Ex. 17). The posters in ORI Exs. 14, 15, and 16 are nearly identical except for the logos in the upper corners. The poster in ORI Ex. 17 contains the same false image, the black image with green specks, with the same label and nearly the same description as the posters in ORI Exs. 14, 15, and

⁴¹ In this case, there is no dispute that all the alleged false materials related to PHS funded research or proposals for PHS funding. Therefore, I do not address the legal issue that may exist under 42 C.F.R. § 93.102(b)(2), i.e., whether research for which PHS funding is denied may be the basis for a research misconduct charge.

16, and the poster in ORI Ex. 17 is in a portrait rather than a landscape orientation like the other posters. I have found that the images in all the posters are false, a fact with which Respondent agrees.

Research misconduct for which administrative actions are authorized are the intentional, knowing, or reckless use (42 C.F.R. § 93.104(b)) of false, fabricated, or plagiarized materials “in proposing, performing, or reviewing research, or in reporting research results” (42 C.F.R. § 93.103). “Reporting” is not defined under 42 C.F.R. pt. 93. For reasons already discussed, I give the term its plain meaning: the act of giving a detailed account or statement, or the record of proceedings of a meeting or session.⁴² Each of the posters indicates at the bottom of the poster that the information is from PHS funded research. ORI Exs. 14-17. ORI has presented the posters but no testimony that the posters were actually presented or used to report PHS funded research. ORI apparently elected to rely upon an inference based on the existence of the posters that they were actually presented or released and thereby, reported PHS funded research results. Respondent does not deny that the VA2009 (ORI Ex. 15) and VA2010 (ORI Ex. 16) posters were presented. He testified that there were poster presentations for VA2009 and VA2010. Tr. 447, 797. He does not deny that the images in the VA2009 and VA2010 were falsely labeled or described, but Respondent asserts that when the posters were prepared he had no reason to question the accuracy of the images that he now agrees are false. Tr. 798. Respondent testified that there was a 2008 Winter Brain poster that was presented, though not by him, and he contributed to the poster, but that poster is not at issue before me. However, he testified that there was no poster presented for Winter Brain 2009. Tr. 692-93, 812. Respondent testified that he never presented a poster at a Winter Brain conference; he was always selected to do an oral presentation. Respondent asserted that he had no idea why his name was on the Winter Brain and World Congress posters and as far as he knew the posters were never generated, which I take to mean as far as he knew they were never printed. He testified that for the World Congress 2010 which was in Korea, he did a thorough oral presentation, not a poster presentation. Tr. 397-400, 424, 486, 693, 796-98. Respondent specifically excluded the VA posters VA2009 and VA2010 (ORI Ex. 15, 16) from his denial. Tr. 400. I have no reason to reject Respondent’s testimony and I find that the VA2009 and VA2010 posters (ORI Exs. 15, 16) were published or presented and reported false information about PHS funded research. However, I find that no inference is possible that the other posters were actually ever published or released and, for that reason, they do not constitute a report related to PHS funded research and are not the basis for a charge of research misconduct. Although Respondent’s curriculum vitae lists two peer-reviewed abstracts for the World Congress in 2010, I cannot infer from that listing as ORI urges me to, that WC2010 was actually presented and thereby reported the results of PHS funded research. R. Ex. 24 at

⁴² Merriam-Webster.com (last updated May 23, 2018).

12; ORI Br. at 21. I note that during his statement to ORI investigators Runko and John Dahlberg, Director of the Division of Investigative Oversight, ORI, Respondent asked whether the WSU Investigation sent ORI the posters or the data files. Runko responded that they received data files from WSU. ORI Ex. 53 at 51. Therefore, the ORI source for the poster images does not establish whether the posters, other than VA2009 and VA2010, were ever presented.

(c.) ORI has made a prima facie showing that the false images or graphs used in materials cited in the ORI Charge were used in violation of the standard practices for the PHS research community established by the Secretary in 42 C.F.R. pt. 93.

Respondent's position has been consistent. He asserts that he did not insert the images with false labels and descriptions in any of the documents cited in ORI Charge 1a. He admits that the images are false, but asserts that he did not know they were false and he denies he intended to use false images. He also argues that he did not recklessly use or permit the use of false images in his grant proposals or the article. In responding to my questions at hearing, Respondent stated he had no way to know whether an image that was created before his arrival at the laboratory or that data from another source was "concocted or not." Tr. 808-09. Our dialogue continued as follows:

JUDGE SICKENDICK: So if you choose to - - if you choose to present data in whatever form, whether it's an image, a table or whatever, what I'm hearing you say is you don't feel like you had any responsibility to verify the accuracy of the data before sending that off to NIH as part of the consideration for the submittal, to approve a grant? Is that - - is that what you want me to think you said?

THE WITNESS [RESPONDENT]: Well, what I'm saying is, is that while I am responsible as the principal investigator, is that at the end of the day, I take it on good faith that my collaborators have already gone through the validation process. I don't think that it's common practice for a scientist that receives data from a collaborator, to ask them, to show them, to validate the data.

Tr. 809. In post-hearing briefing, Respondent argues that in the research community it is acceptable for scientists collaborating on a project to rely upon each other's work in good faith. R. Br. at 12, 16-22. Dore-Duffy's sworn statement to the VA investigation shows that she certainly thought it is permissible to include materials from others without verification of the truth or accuracy of those materials as she stated that she did not bother

to verify materials she obtained from Respondent or Rafols that she used in her grant applications. ORI Ex. 66 at 22-23. I do not accept Respondent's argument and his and Dore-Duffy's testimony as sufficient to rebut the ORI prima facie showing that Respondent's conduct was a significant departure from accepted practices in the relevant PHS research community.

I have concluded that Congress identified a research community – the PHS research community – that is composed of all institutions and individuals who propose PHS funding, perform, review, or report research results. The Secretary has established accepted and required practices for the PHS research community. Institutions and members of institutions who apply for and/or receive PHS funds have an affirmative duty to protect PHS funds from misuse by ensuring the integrity of all PHS funded work, including the responsibility to respond to and report research misconduct. 42 C.F.R. § 93.100(b). Whether or not relevant research communities can be identified that are subsets of the larger PHS research community, is a question of fact. There is evidence in this case that additional relevant research communities might be those researchers who engage in the type of research carried on by Respondent or collaborate in performing such research. WSU and VA in Detroit and the national VA organization may all be relevant research communities. Several research communities can be identified and determined to be relevant as in this case in addition to the overarching PHS research community. The question then is what the accepted practices of these relevant research communities are, or conversely, what practices are not acceptable, which is what is actually required to be shown by ORI.

The Secretary's regulations control the PHS research community, and the Secretary has delegated authority to both establish accepted practices and enforce compliance with those accepted practices by imposing administrative actions for violations. Individuals and institutions who apply for PHS support are on notice by virtue of 42 C.F.R. pt. 93 that they have an affirmative duty to protect PHS funds and ensure the integrity of PHS research. They are also on notice that they are subject to administrative action for research misconduct. Individuals and institutions who apply for PHS support are part of the PHS research community and voluntarily agree to comply with the accepted practices within that community as those practices are established by 42 C.F.R. pt. 93.

I conclude that the drafters of 42 C.F.R. pt. 93, in requiring ORI to identify the relevant community and accepted practices within the relevant community, intended that whatever relevant sub-communities were identified could not have accepted practices inconsistent with or violative of the accepted practices of the PHS research community. To accept practices of a scientific community inconsistent with those required by 42 C.F.R. pt. 93 would prevent effective enforcement and violate the PHS research community's commitment to protect PHS funds and the integrity of PHS research.

The assertions of Dore-Duffy and Respondent that relying upon the work of others in good faith and using the work of others without verification is an accepted practice in the WSU, VA, or Detroit-area research communities, may be accurate. However, that accepted practice cannot stand to the extent it conflicts with the accepted practice within the PHS research community that prohibits the use of false, fabricated, or plagiarized materials in proposing, performing, reviewing, or reporting PHS research. In this case, Respondent's and Dore-Duffy's testimony that it is acceptable to rely upon the work of others without verification is un rebutted by ORI. However, when that practice results in including false reports of PHS funded research in grant applications, articles, and posters and amounts to research misconduct, the accepted practice may not be accepted as a defense to the regulatory requirement or sufficient to rebut the ORI prima facie showing on this element.

(d.) ORI has made a prima facie showing that Respondent recklessly used the false images or graphs in the materials cited in the ORI Charge, i.e., without exercising proper care or caution or with disregard or indifference to the risk that the materials were false.

Research misconduct for which administrative actions are authorized are the intentional, knowing, or reckless use (42 C.F.R. § 93.104(b)) of false, fabricated, or plagiarized materials "in proposing, performing, or reviewing research, or in reporting research results." 42 C.F.R. § 93.103.

The WSU Investigation and Runko did not uncover direct evidence⁴³ that Respondent intentionally, knowingly, or recklessly included false images in any grants, articles, and posters. Respondent did not admit that he used or directed the use of false materials, and while ORI points to various email, Respondent's statement to the WSU Investigation, and various other evidence, none is direct evidence that Respondent used or directed the use of false material intentionally, knowingly, or recklessly. Rather, ORI must rely upon inferences based on the evidence of record to establish that Respondent engaged in conduct that amounted to research misconduct. The same is true for all the charges.

On August 6, 2012, Respondent was interviewed by Runko and Dahlberg (ORI Director of the Division of Investigative Oversight) and a transcript was made. ORI Ex. 53. The statement reflects that the interview may have been at the request or suggestion of Respondent as Dahlberg opened the interview by asking Respondent what he wanted to cover. ORI Ex. 53 at 2. Respondent, Dahlberg, and Runko refer throughout to the report

⁴³ Direct evidence is evidence based on personal knowledge or observation that proves a fact without the need for an inference or presumption. *Black's Law Dictionary* 596.

of the WSU Investigation completed on November 30, 2011 and Allegations 1 through 6 contained in that report, which are in part the basis for the ORI Charges that are organized and numbered differently. ORI Ex. 1 at 3-4, 8. During the interview, Runko, Dahlberg, and Respondent refer to exhibit numbers of various documents from the WSU Investigation, only a few of which are in the record before me. No exhibits are included with the statement in ORI Ex. 53. Other documents referred to during the interview are not identified by an exhibit number or a sufficient description to identify whether the documents used during the interview are actually in evidence before me. ORI Ex. 53 at 7. For example, during the interview Runko refers to various pages of a “slide set,” but that slide set is not attached to Respondent’s statement, and based on my comparison of the minimal description in the statement and Runko’s analysis in ORI Ex. 19, the slide set used in the interview is not part of Runko’s analysis. The slide set is also not identifiable among the other documentary evidence in the record. ORI Ex. 53 at 5, 85.

However, some facts can be gleaned from the interview of Respondent by ORI. Regarding WSU Allegation 1, Respondent stated that the image in the 2011 Neurological Research article, NR2011-1 Figure 3 (ORI Ex. 11 at 4) was incorrectly labeled and described as reflecting the effect of clazosentan and that the correct label and description was anti-calponin antibody as in the grant application R01 NS064976-01A1 Figure 8 (ORI Ex. 7 at 12). ORI Ex. 53 at 4. Respondent stated he had no reason to suspect the erroneous labeling until he became aware of the allegation of research misconduct. ORI Ex. 53 at 8. Respondent stated that as soon as the error was identified the journal was contacted to make a correction, which is consistent with the evidence. ORI Ex. 53 at 6, 10; R. Ex. 3. Respondent stated he took responsibility for the erroneous listing of clazosentan instead of anti-calponin antibody because he was the “corresponding author on that paper.” ORI Ex. 53 at 10. Respondent discusses a Winter Brain poster that Runko represented was presented in 2008, to which Respondent agreed. But the Winter Brain poster referred to in ORI Charge 1 is alleged to be from 2009 (ORI Ex. 14). ORI Ex. 53 at 4-5. Respondent referred to the computer in his office as his computer but he stated that it was a “shared data computer.” ORI Ex. 53 at 4; Tr. 289. Regarding WSU Allegation 2, Respondent explained that he never intended to agree during the WSU Investigation that the Fluoro-Jade image (black with green or white spots that is the basis for ORI Charge 1) depicted hippocampus. He stated the WSU investigators showed him a PowerPoint™ slide with a title and no image and he was asked to state what the title meant. He stated that he knows the difference in the appearance of hippocampus samples and sensorimotor cortex samples and there is no way that the Fluoro-Jade image was hippocampus. ORI Ex. 53 at 11-12. He stated that the image was mislabeled as BQ-788 in Rafols’ 2010 Neurological Research paper on which Respondent was listed as co-author. ORI Ex. 53 at 12; ORI Ex. 67 at 18 (ORI Charge 1b). Regarding WSU Allegation 3 (relates to ORI Charges 2, 2a, 2b, ORI Ex. 67 at 24-26), Respondent stated that in the 2010 Neurological Research paper (pages 209-14), which was Rafols’ paper, Figure 4A should have been labeled BQ-123 and BQ-788. But the figure in the 2011 paper was labeled as clazosentan. ORI Ex. 53 at 16. Respondent asserted that BQ-123

and clazosentan results were very similar, and until the allegation of research misconduct, no one brought the error to his attention. ORI Ex. 53 at 19-21. Respondent stated regarding the 2010 Neurological Research article that the systolic blood pressure curves were mislabeled in that Panel A was labeled BQ-123 and Panel B was labeled BQ-788. Respondent stated that the one that is accurate is Panel B on page 11, but it was never clarified whether he was referring to the article, which does not appear to be the case as the page range for the article is 209 through 214, or the set of images Runko previously referred to which does not seem to match his analysis (ORI Ex. 19) and no set of images was attached as part of Respondent's statement. ORI Ex. 53 at 26. Respondent told Runko and Dahlberg that he did not know who created the "figure" in the 2010 Neurological Research paper, but he also stated that as the corresponding author he was responsible for getting the figures in the article. Respondent also stated he was responsible for putting the figures in his grants [cited in ORI Charge 1]. ORI Ex. 53 at 28. Respondent revealed that when he was terminated he returned to the laboratory to retrieve his personal effects, and he had about an hour to copy files from his and Rafols' computers. There was no follow-up questioning by Runko and Dahlberg to Respondent's revelation that he accessed Rafols' computer. ORI Ex. 53 at 36. Regarding WSU Investigation Allegation 4-2, which corresponds to ORI Charge 3a, Respondent agreed that the reference to Bosentan in labeling or describing the images listed was in error and the correct drug was BQ-788 and the correct number of animals used in the experiments was six. ORI Exs. 1 at 22; 53 at 39-41. Regarding WSU Investigation Allegation 4-3, which corresponds to ORI Charge 3b, Respondent conceded that files may have been insufficiently labeled, resulting in the wrong image being used, but he stated the results are nearly identical though not the same and he admitted an error. ORI Exs. 1 at 23; 53 at 47-49. Respondent told Runko and Dahlberg that all the western blot images were provided by Dore-Duffy. ORI Ex. 53 at 83. The remainder of Respondent's statement (ORI Ex. 53 from pages 91 through 117) only indicates "Man" as the speaker and does not identify whether Respondent, Runko, or Dahlberg is the speaker so it is impossible to distinguish Respondent's statements and these pages are entitled to no weight.

ORI argues that "email evidence provides the 'smoking gun' in this case and shows Respondent's role in labeling falsified images or selecting images for use in grants, publications, and posters and demonstrates he knew or should have known of the falsified images."⁴⁴ ORI Reply at 10, 13-18. But that is far from the case. ORI engages in a convoluted and misleading evaluation of various email to which Respondent was a party to support its position that Respondent engaged in what ORI characterizes as the false reporting of images or that he "knew or should have known" were false. ORI Reply at 11-16. In fact, the email shows Respondent was engaged in the editing of materials that

⁴⁴ ORI's use of a "knew or should have known" standard is in error as that standard is not adopted by the regulations or applicable in this case.

he has conceded included falsely labeled images. The evidence shows that Respondent possessed at least one falsely labeled image that was subsequently published. But ORI has failed to convince me to infer that, based on the two facts established, it is more likely than not that Respondent knew the images used in the grants were falsely labeled when the grants were submitted and that he knew the images published were falsely labeled when published.

In the alternative, ORI needs to show that Respondent recklessly used the falsely labeled images. ORI placed various email in evidence as ORI Exs. 23-34, 40-50, 61, 68. ORI Ex. 23, a May 24, 2010 email from Respondent to Donald Kuhn, forwarded a manuscript and figures, including a copy of the image referred to in ORI Charge 1a as NR2011-1 Figure 3 (2011 Neurological Research article, ORI Ex. 11 at 4). Attached to the email was the Fluoro-Jade image which Respondent now concedes was falsely labeled “TBI + Clazo” (ORI Ex. 23 at 4) and the description for the image (ORI Ex. 23 at 19). The email shows that Respondent had the false image in advance of the publication of the article. However, the email does not support an inference that Respondent knew at the time that the image was false. ORI Ex. 24 is an email dated May 24, 2010, to “manueldujovny@hotmail.com” which also includes the falsely labeled image and description. This email also shows that Respondent had the false image in advance of publication but does not support the inference he knew it was false. ORI Ex. 24 at 4, 19. ORI Ex. 48 is a copy of an email from Respondent to Rafols dated May 20, 2010, forwarding the article with the image descriptions but no image. ORI Ex. 25 is a copy of a May 19, 2010 email from Respondent to William M. Armstead with the article, false image, and description. ORI Ex. 25 at 4, 19. ORI Ex. 40 is an email thread including Armstead’s response email on May 19, 2010. ORI Ex. 41 is an email from Respondent to staff directing that they pull references from PubMed and other instructions with two draft articles attached. None of these email show that Respondent knew that there were false materials included in either the email or the draft articles. ORI Ex. 26 is an October 22, 2009 email from Respondent to himself and it does not contain or refer to any allegedly false materials. ORI Ex. 27 is an October 6, 2009 email thread between Respondent and a contact at Actelion Pharmaceuticals, Ltd., which provided clazosentan for experiments in Respondent’s laboratory. This email thread shows that Respondent shared findings and material but not that Respondent knew any of the research findings or materials attached to the email were false. Email in ORI Exs. 28, 29, 30, 31, 32, 33, 34, 42, 43, 44, 45, 46, 47, 49, and 50 (Respondent’s curriculum vitae or resume) do not show that Respondent knew any materials were false. I further note that none of the email are charged by ORI as research misconduct. Not only do the email presented to me not include a smoking gun as suggested by ORI, the email are not particularly probative on the issue of whether Respondent actually knew that any of the material he was sharing was false or that there was a risk that they were false.

Dore-Duffy’s testimony as part of the VA investigation was given under affirmation but not subject to any cross-examination. Her testimony is not helpful on the issue of

Respondent's intent or knowledge. Dore-Duffy testified to the VA investigation team that she had no idea how Respondent obtained figures he gave her. The VA investigation team showed Dore-Duffy various images or exhibits that were not described with sufficient detail for me to identify them as being in the record before me. Exhibits from the VA investigation were referred to, but they are not in evidence before me. I cannot correlate the vague references to exhibits in Dore-Duffy's testimony to any substantive evidence before me. ORI Ex. 66 at 6-9. Dore-Duffy testified that she accepted on faith whatever Respondent gave her and she had no idea why the same image might have two different labels in different documents. ORI Ex. 66 at 11-14. She testified that her name actually appeared on many grant applications she never even saw, particularly from the period when she was an assistant professor. ORI Ex. 66 at 17. She testified that the images that she was shown during her testimony were not hers because she did not do exercise conditioning or Fluoro-Jade and the western blot images were not to her standards. She testified that Respondent, Rafols, or someone in their laboratory provided the images. But she asserted that Respondent gave her the images because no one else from his laboratory gave her anything except Rafols, but she states that she was not shown anything by the VA investigation team that Rafols provided. ORI Ex. 66 at 18-20. Dore-Duffy became defensive at one point:

DR. MAJUMDAR: So when you were the PI, you did sort of, you know, retry, probably, to a certain extent, that there were cut and paste and things like that?

THE INTERVIEWEE: Well, first of all, I think that's an unfair question. If you're putting -- if you're collaborating with individuals and you're putting together a grant, there's a certain amount of respect and I had no indications that would ever make me question how somebody did it. If it's preliminary data -- and I'm saying it's preliminary data -- it's from a system that I'm not on. Now, maybe, I wouldn't have exactly done it myself. But to the best of my knowledge, it was displaying what information I thought it was displaying. Whether I would choose to publish that without additional information on the figure is a different question. But I had no indication that any of these um -- that there was anything wrong with any of these figures. And I'm beginning to think, Am I on trial here? Then, you know, why am I --

MS. FOX: No. You are not --

DR. MAJUMDAR: No. No.

MS. FOX: You are not in any way.

THE INTERVIEWEE: Well, I'm telling you to the best of my recollection what happened. I made a decision to allow something to be in a grant because, at least as presented in the figure, it did exemplify what we were saying in the preliminary data portion or the background data portion. That's all I can say. As to how they were prepared in Dr. Rafols' and Kreipke's lab -- and I want to stress, this is always a collaboration on my part between Dr. Rafols and Dr. Kreipke. Dr. Rafols and I have known each other for 25 or 30 years. And because of that association, I would have accepted what came out of that laboratory without question unless I saw something.

* * * *

DR. MAJUMDAR: Yes. Thanks for clarification. Thank you.

ORI Ex. 66 at 21-23. In short, Dore-Duffy did not bother to verify materials she obtained from Respondent or Rafols that she used in her grant applications. But, Dore-Duffy's testimony does not show that Respondent intended to provide Dore-Duffy false research results or that he knew that materials he provided to Dore-Duffy were false.

Turning to other evidence offered by ORI, ORI Ex. 61 is an email thread: an August 6, 2012 email from Runko to Respondent requesting an original laboratory notebook to replace the copy Runko had; Respondent's August 7, 2012 request for guidance; Runko's August 7, 2012 response; Respondent's August 7, 2012 response agreeing to mail the notebook; an August 8, 2012 response from Runko explaining how to mail or ship the notebook to ORI; and Respondent's August 10, 2012 email that he was shipping the notebook with a description of the notebook. According to Respondent's email, the notebook was found in Rafols' office in June 2011, it covers the period October 2007 to February 2010, and includes entries by multiple people. ORI describes ORI Ex. 60 as a copy of the laboratory notebook Respondent brought to his interview with ORI on August 6, 2012. Government's List of Admitted Office of Research Integrity Exhibits (ORI Appendix 1) at 13. Based on the date of Respondent's ORI interview and the email thread between Runko and Respondent, I infer that ORI Ex. 60 is a copy of the laboratory notebook that Respondent took to the interview, the original of which he subsequently shipped to Runko. ORI Ex. 62 is the October 24, 2012 report of a forensic examination of the notebook. The forensic examination found that entries in the notebook had been overwritten, dates had been changed, and different inks were used. Most of the anomalies identified by the forensic examination would be apparent to the eye of a layperson. The forensic examiner did not opine whether all entries were made by a single

person, a typical question in a forensic document examination of a document with handwritten entries. The forensic examiner also did not opine whether the entries in the notebook were made at about the same time, another common question on forensic handwriting analysis. Laypersons are generally competent to compare handwriting samples. It appears to me that several different people made handwritten entries in the notebook. It is not possible for me to determine over what period of time the entries were made other than to consider the dates listed, which may or may not be accurate. The notebook contains Respondent's name in script (ORI Ex. 60 at 2) but I have no sample of Respondent's writing of his name to compare. Much of the handwriting in the notebook is not similar to Respondent's written name. ORI Ex. 60 at 2, 7, 28-30, 40, 43. Most important is that this notebook, which contains what appears to be raw data from observations, contains no information that helps me decide whether or not Respondent knowingly, intentionally, or recklessly used false images or materials to apply for funding from PHS or to report the results of research. To the extent ORI offers the notebook in an effort to challenge Respondent's credibility, ORI fails because ORI does not show how the notebook reflects negatively upon Respondent's credibility. Changing date entries and overwriting may be completely benign. Further, there is no charge that Respondent actually falsified research or research results such as those reflected in the notebook. The charges are that he re-used false images and graphs that he may or may not have created.

I conclude that ORI has failed to present sufficient evidence to show that it was more likely than not that Respondent knew the images and materials listed in any of the ORI charges were false. ORI has also failed to show it is more likely than not that Respondent actually inserted any of the falsely labeled or described images in the grant proposals, the article, or the posters.

Therefore, it is necessary to examine what appears to be the real ORI theory for Respondent's liability. Based on ORI pleadings that theory is that, even if Respondent did not insert the false material and he did not intentionally or knowingly use false material in proposing, performing, reviewing, or reporting PHS funded research, he is still liable as a PI, author, editor, or contributor for recklessly permitting false material to appear in grant proposals, an article, and posters.

The remaining ORI theory is that Respondent is responsible or liable for the contents of the grant applications, the article, and the posters in ORI Charge 1a, because he was listed as a PI, author, creator, or the document was attributed to Respondent on some basis. ORI Br. at 12-25; ORI Reply at 9-17. This ORI theory applies to all the charges and the grant applications, posters, articles, and book cited in those charges. In its broadest sense the ORI theory could support the argument that anyone listed as contributing to a grant, article, or poster could be held liable for any false, fabricated, or plagiarized content in materials described in 42 C.F.R. § 93.102(b)(1) and (2). The ORI theory and approach is not inconsistent with 42 C.F.R. pt. 93.

The regulations impose upon institutions and institutional members who seek or receive PHS funding an affirmative duty to protect PHS funds from misuse and primary responsibility for responding to and reporting allegations of research misconduct. 42 C.F.R. § 93.100(b). Institutional member is defined by 42 C.F.R. § 93.214 to include anyone employed by, an agent of, or affiliated by contract or agreement with an institution that applies for or receives PHS support within the meaning of 42 C.F.R. § 93.213. Therefore, virtually anyone engaged with an institution applying for or that has received a PHS grant is potentially liable for research misconduct. The regulations do not further define who is potentially liable for research misconduct. In this case, under the broadest possible application of 42 C.F.R. pt. 493, ORI could proceed against anyone listed on a grant, article, or poster with Respondent. However, ORI has elected to proceed only against Respondent. Respondent is rightfully concerned that he has been singled out by WSU and ORI while others potentially responsible have not been subject to investigation. However, Respondent benefits from the WSU and ORI failure to examine others potentially involved in the research misconduct to the extent that he can defend on the basis that others not before me, did the act. But such a defense is small consolation given the cost and career impact of being subject to research misconduct proceedings.

The issue to be resolved is whether Respondent may be held liable for research misconduct in PHS grant proposals, articles, posters, or a book on which his name appears and in which there is false, fabricated, or plagiarized material, even if the evidence does not show it is more likely than not that he intentionally or knowingly used the false, fabricated, or plagiarized material in the questioned document. The answer is clearly yes. So long as the required act of proposing, performing, reviewing, or reporting PHS supported research occurred and false, fabricated, or plagiarized materials were used, under the broadly drafted 42 C.F.R. pt. 93, one listed as having responsibility for the action such as a PI or author may be found liable for the research misconduct, even if he or she committed no act other than “recklessly” permitting the inclusion of false, fabricated, or plagiarized material in proposing, performing, or reviewing research, or in reporting research results. 42 C.F.R. § 93.103.

Therefore, it is necessary to examine whether the ORI evidence shows it more likely than not that Respondent recklessly used falsely labeled or described images in proposing research for PHS funding through his grant applications or in reporting PHS funded research through the article and posters.

Charge 1 and Charge 1a allege that Respondent “re-used” false images in the grants, the article, and the posters. ORI Ex. 67 at 16. The fact the images were false is established.

ORI has failed to meet its burden to show it is more likely than not that Respondent knew that the images as labeled and described were false when submitted as part of the grant

proposals, when the article was submitted for publication, and when the two posters were presented or reported. ORI has also failed to present sufficient evidence that shows it is more likely than not that Respondent actually inserted the falsely labeled and described images in the grant proposals, the article, and the posters. Therefore, ORI has failed to show that Respondent intentionally or knowingly used falsely labeled or described images.

Whether Respondent engaged in research misconduct as charged by recklessly permitting the inclusion of false material in his grant applications, the article, the posters, and the book must be addressed as to all charges. The specific issue is whether Respondent “re-used” false images, either falsely reporting PHS funded research results as in the case of the articles, posters, and book or in applying for grants. Respondent does not concede that he inserted any of the false images in any of the documents in issue. Further, ORI has not shown that Respondent actually created the false images and graphs or prepared the documents and inserted the false images or that he directed others to do so.

The applicable statutes do not address research misconduct or liability for research misconduct. 42 U.S.C. §§ 216, 241, 289b. The regulations at 42 C.F.R. pt. 93 do not specifically provide that a PI, author, editor, or other contributor is presumptively liable for the contents of grant proposals, articles, posters, or reports of PHS funded research in other formats. The drafters of 42 C.F.R. pt. 93 certainly understood presumptions and how to establish a presumption under the regulations as they created the presumption of research misconduct in the event of intentional, knowing, or reckless destruction, failure to maintain, or failure to produce questioned documents. 42 C.F.R. §§ 93.106(b)(1); 93.516(b)(1); 75 Fed. Reg. at 28,371-72.⁴⁵ I conclude that there is no statutory or regulatory presumption that a PI, author, editor, or other contributor is presumptively liable for the presence of false material in a grant proposal, article, poster, or similar reports of PHS funded research. I am not willing to find a presumption exists where one is not established by Congress or the drafters of the regulations, particularly where the drafters of the regulation demonstrate knowledge of legal presumptions and their effect and apparently elected not to establish a presumption.

Nevertheless, even absent a presumption, I conclude that the basic fact that one is the PI on a grant proposal or a first listed author of a report, whatever the form of the report may be, including published articles, books, or presented posters, supports the inference that that person is responsible for the content of the report. The inference is consistent with the testimony of Respondent. The fact that WSU and ORI elected not to pursue Rafols,

⁴⁵ The drafters state that they eliminated the rebuttable presumption but that is not accurate. The drafters simply added to the ORI burden to present evidence necessary to trigger the presumption.

who is listed as the PI on R01 NS039860-09A2 in ORI Charge 1a and other individuals listed as PIs in other ORI Charges, may appear to be inconsistent with the inference that a PI may be liable for false material in a grant proposal. However, I conclude that the inconsistency in this case is insufficient to negate or rebut the inference of liability as the decision not to pursue Rafols and other PIs as subjects of research misconduct appears to be within the discretion of WSU and ORI under the regulations; and I do not accept that exercise of discretion as being inconsistent with the inference that a PI or first-listed author is responsible and liable.

Having concluded that ORI failed to show that Respondent intentionally or knowingly used false materials, I must consider whether the research misconduct that occurred in this case was committed recklessly. The regulations do not define recklessly and I previously adopted the definition that research misconduct may occur if one recklessly:

Used materials without exercising proper care or caution and disregarded or was indifferent to the risk that the materials were false, fabricated or plagiarized.

I conclude that ORI has made a prima facie showing that Respondent's use of false images in the grant applications, the article, and two of the posters listed in ORI Charge 1a, was reckless by a preponderance of the evidence. In his statement to the WSU Investigation, Respondent stated that he did not verify data or scrutinize the false images before including the false materials in his grant applications, the article, and the two posters. He stated that he knew Rafols and anybody else would have taken on faith that the images as labeled and described were accurate representations. ORI Ex. 64 at 38, 40, 75-76. The question is did Respondent fail to exercise proper care or caution, did he disregard, or was he indifferent to the risk that materials that were included in the grant applications, the article, or the posters for which he was the PI or the first listed author were false?

The Secretary has imposed upon institutions and researchers a heavy responsibility to protect PHS funds and ensure the integrity of PHS research. Grant applications seek PHS funding, often significant amounts, and based on all the testimony it is clear that researchers rely upon the research of their predecessors. False information in grant applications may result in expenditure of PHS funds or mislead other researchers as to the results of PHS funded research. Therefore, including data, images, and other materials without validation of the accuracy of the information constitutes failure to exercise proper care or caution and disregard or indifference to the risk for potential false information, and a violation of the responsibility institutions and researchers accept to protect PHS funds and the integrity of PHS research.

Respondent knew that in 2008, Ted Petrov, his original mentor, had been terminated for personal reasons. All of Petrov's computers and laboratory notebooks were sequestered by WSU at that time. Respondent also knew that many images were done originally in

2007 or 2008 when Petrov headed the laboratory. ORI Ex. 53 at 8-9, 55, 59-60, 81-82; ORI Ex. 64 at 15-16. Respondent was aware of disorganization and lack of record keeping when he joined the laboratory and for which he became the leader. ORI Ex. 53 at 32. Respondent was aware that virtually everyone that worked in the laboratory had access to all the computers and laboratory notebooks. ORI Ex. 53 at 4-5, 37, 38, 86; ORI Ex. 64 at 12-13, 28, 141-42; Tr. 659-68. Respondent told the WSU Investigation that in 2010, one of his “first missions” was to hire a laboratory administrator, and that is when they started doing oversight in the laboratory. ORI Ex. 64 at 13. Respondent also knew that Reynolds, who was hostile to Respondent, had access to the computers and laboratory notebooks. ORI Ex. 64 at 118, 129-30; 172-73. Based on his knowledge of the state of his laboratory and personnel situations, it was reckless for Respondent to simply assume that materials placed in his grants, articles, and posters were reliable. I have considered Respondent’s arguments of honest error. However, research misconduct occurred as a result of Respondent recklessly including falsely described images in the article referred to as NR2011-1 Figure 3 (ORI Ex. 11 at 4); and the posters VA2009 Figure 6 (ORI Ex. 15) and VA2010 Figure 6 (ORI Ex. 16), resulting in false reporting of PHS funded research. Honest error does not negate or rebut the proof of recklessness. Honest error is also not a defense as there is no question that the images were false and whether or not they were false when included in the grant application, the article, and the posters was not even considered by Respondent who admits he simply assumed that others reliably performed research and truthfully reported the results of research.

I conclude based on the evidence of record, principally the testimony of Respondent which is unrebutted that the images in grant applications R01 NS064976-01A1 Figure 8 (ORI Ex. 7 at 12) and R01NS064976-01A2 Figure 8B (ORI Ex. 2 at 6) were not false. I conclude that Rafols was the PI on grant application R01 NS039860-09A2 Figure 8B (ORI Ex. 5 at 4) not Respondent; and Respondent should not be held liable for any false information in that grant application on the facts of this case. This conclusion applies to all the ORI charges that allege research misconduct in a grant application on which someone other than Respondent was the PI, specifically ORI Charges 1c, 4a, and 4b. Finally, I conclude that the evidence does not show that it is more likely than not that the posters, WB2009 Figure 6 (ORI Ex. 14) and WC2010 Figure 5 (ORI Ex. 17), were published or distributed and, therefore, it has not been established that there was any false reporting of PHS funded research related to those posters. This conclusion applies to all ORI Charges that allege research misconduct related to WB2009 and WC2010, specifically ORI Charges 1b, 1c, 2b, and 3b. Accordingly, I conclude that three instances of research misconduct have been proved under ORI Charges 1 and 1a.

The foregoing discussion of my analysis of the evidence, documentary and testimonial, applies to the analysis of the remaining 15 charges. In the interest of judicial economy and the sanity of the reader, I repeat only the minimum necessary of the foregoing in the discussion for each of the following charges.

(3) ORI Charge 1b: Respondent intentionally, knowingly, or recklessly re-used a single image of Hipp,⁴⁶ 48 hours post-TBI, no treatment, to represent

(a) *controls at 4, 24, or 48 hours post-TBI in smCx in*

R01 NS064976-01A1, Figure 8,

R01 NS064976-01A2 and R01 NS039860-09A2, Figure 8B,

NR2011-1, Figure 3, and

in the posters WB2009, VA2009, and VA2010, Figure 6, and

WC2010, Figure 5; and

(b) *5 nmol BQ-788 treatment post-TBI in smCx in*

NR2010, Figure 5C.

ORI Ex. 67 at 18.

I do not consider ORI Charge 1b to the extent it relates to the grant for which Rafols was the PI (R01 NS039860-09A2, Figure 8B) or the posters (WB2009 and WC2010) based on the foregoing analysis.

ORI Charge 1b alleges that in Respondent's two grant applications, R01 NS064976-01A1 Figure 8 and R01 NS064976-01A2 Figure 8B, the 2011 Neurological Research article (NR2011-1 Figure 3), and posters VA2009 and VA2010 Figure 6, the images had one description but a different description was given in the 2010 Neurological Research article for Figure 5C (NR2010). ORI Charge 1b(a) involves the same images as ORI Charge 1a. The image that is the focus of ORI Charge 1b(b) is different from the images under ORI Charge 1b(a). All the images appear to be of Fluoro Jade but the image under ORI Charge 1b(b) has three panels unlike the images under ORI Charge 1b(a) which only have two panels. ORI has not shown that the images under ORI Charge 1b(a) and 1b(b) are the same images as I reject Runko's opinions. However, Charge 1b actually focuses

⁴⁶ According to Runko the abbreviation is for hippocampus. ORI Ex. 69 at 4.

on the description that accompanies the image rather than the labels that appear on the image itself.

The following table lists the various images from the charge, a description of the type of document in which the image appears as that affects what ORI must prove, and the citation to the ORI exhibit where the document and image may be found.

IMAGE	DESCRIPTION	DATE OF DOCUMENT	ORI EXHIBIT
R01 NS064976-01A1, Fig. 8	Grant Application, Respondent PI	11/17/2008	ORI Ex. 7 at 12
R01 NS064976-01A2, Fig. 8B	Grant Application, Respondent PI	3/13/2009	ORI Ex. 2 at 6
R01 NS039860-09A2, Fig. 8B	Grant Application, Rafols PI	6/29/2009	ORI Ex. 5 at 4
NR2011-1, Fig. 3	Christian W. Kreipke et al., <i>Clazosentan, A Novel Endothelin A Antagonist, Improves Cerebral Blood Flow and Behavior After Traumatic Brain Injury</i> , 33 Neurological Research 208, 211 (2011)	2011	ORI Ex. 11 at 4
WB2009, Fig. 6	Winter Brain Poster	Undated	ORI Ex. 14
VA2009, Fig. 6	VA Presentation Poster	Undated	ORI Ex. 15
VA2010, Fig. 6	VA Presentation Poster	Undated	ORI Ex. 16
WC2010, Fig. 5	World Congress Poster	Undated	ORI Ex. 17
NR2010, Fig. 5C	Christian W. Kreipke et al., <i>Differential Effects of Endothelin Receptor A and B Antagonism on</i>	2010	ORI Ex. 10 at 5

	<i>Cerebral Hypoperfusion Following Traumatic Brain Injury,</i> 32 Neurological Research 209, 213 (2010)		
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(a.) ORI has made a prima facie showing that there are false images based on false descriptions or labeling in the materials cited in the ORI Charge.

Respondent agreed at hearing in response to my questioning that all the images were incorrectly described. Tr. 802-03. During his interview as part of the WSU Investigation, Respondent agreed that the wrong image was used in the NR2010 article as Figure 5C. According to Respondent the image represents Fluoro-Jade staining following TBI without any treatment rather than the description given in the article. ORI Ex. 64 at 68-71.

Accordingly, I conclude that false materials in the form of incorrectly described or labeled images were included in Respondent's two grant applications, the two articles, and the two posters.

(b.) ORI has made a prima facie showing that some of the materials cited in the ORI Charge were used in applying for PHS funding or in reporting PHS funded research.

False materials were used in applying for PHS funding through Respondent's two grant applications. False materials were included in the two articles and two posters resulting in the false reporting of PHS funded research.

(c.) ORI has made a prima facie showing that the false images or graphs used in materials cited in the ORI Charge were used in violation of the standard practices for the PHS research community established by the Secretary in 42 C.F.R. pt. 93.

Using images that are false or falsely labeled or described violates the standard practices of the PHS research community.

(d.) ORI has made a prima facie showing that Respondent recklessly used the false images or graphs in the materials cited in the ORI Charge, i.e., without exercising proper care or caution or with disregard or indifference to the risk that the materials were false.

For reasons already discussed, Respondent recklessly used falsely described images in grant applications for which he was responsible as the PI or in articles or posters for which he was the first-listed author.

I conclude based on the evidence of record that it is more likely than not that Respondent committed research misconduct in his two grant applications, R01 NS064976-01A1 Figure 8 and R01 NS064976-01A2 Figure 8B; the 2011 Neurological Research article (NR2011-1 Figure 3); posters VA2009 and VA2010 Figure 6; and the 2010 Neurological Research article (NR2010 Figure 5C).

I have considered carefully Respondent's arguments that the errors reflected by the charge are simply honest error. Honest error does not negate or rebut the proof of recklessness. Honest error is also not a defense as there is no question that the images were false and whether or not they were false when included in the grant applications, the articles, and the posters was not even considered by Respondent who admits he simply assumed that others reliably performed research and truthfully reported the results of research.

Accordingly, I conclude that six instances of research misconduct have been proved under ORI Charge 1b.

(4) ORI Charge 1c: Respondent intentionally, knowingly, or recklessly re-used a single image of smCx, 24 hours post-TBI, BQ-123 treatment, to represent

(a) 0.1 mg/kg BQ-123 treatment, 4 hours post-TBI in smCX in

R01 NS064976-01A1 and R01 NS064976-01A2, Figure 7, and

R01 DK090549-01, Figure 4 (panel 3);

(b) BQ-123 treatment, 48 hours post-TBI in smCx in

NR2010, Figure 5B, and in

the posters SFN2008, WB2009, VA2009, and VA2010, Figure 3; and

(c) 1.0 mg/kg clazosentan treatment, 24 hours post-TBI in smCx in

R01 NS073603-01, Figure 6 (panel 3).

ORI Ex. 67 at 20.

The following table lists the various images from the charge, a description of the type of document in which the image appears as that affects what ORI must prove, and the citation to the ORI exhibit where the document and image may be found.

IMAGE	DESCRIPTION	DATE OF DOCUMENT	ORI EXHIBIT
R01 NS064976-01A1, Fig. 7	Grant Application, Respondent PI	11/17/2008	ORI Ex. 7 at 11
R01 NS064976-01A2, Fig. 7	Grant Application, Respondent PI	3/13/2009	ORI Ex. 2 at 5
R01 DK090549-01, Fig. 4, Panel 3	Grant Application, Sima PI	2/5/2010	ORI Ex. 4 at 2
NR2010, Fig. 5B	Christian W. Kreipke et. al., <i>Differential Effects of Endothelin Receptor A and B Antagonism on Cerebral Hypoperfusion Following Traumatic Brain Injury</i> , 32 Neurological Research 209, 213(2010)	2010	ORI Ex. 10 at 5
SFN2008, Fig. 3	Society for Neuroscience Poster	Undated	ORI Ex. 13
WB2009, Fig. 3	Winter Brain Poster	Undated	ORI Ex. 14
VA2009, Fig. 3	VA Presentation Poster	Undated	ORI Ex. 15
VA2010, Fig. 3	VA Presentation Poster	Undated	ORI Ex. 16
R01 NS073603-01, Fig. 6, Panel 3	Grant Application, Rafols PI	6/3/2010	ORI Ex. 9 at 3

I do not consider the allegations of ORI Charge 1c related to R01 DK090549-01 Figure 4, Panel 3 and R01 NS073603-01 Figure 6, Panel 3 because Respondent was not the PI for

those grant applications. ORI Exs. 4 at 1; 9 at 1. I do not consider the Winter Brain 2009 (WB2009) poster as ORI has failed to show that it was ever published or presented and that false reporting of PHS funded research occurred. Respondent testified that he did not present the poster referred to as SFN (Society for Neuroscience) 2008 (ORI Ex. 13) and he had not been a member of that organization since his graduate studies. Tr. 396-400, 811. Respondent's testimony is un rebutted and I have no reason to reject his testimony on this point as not being credible. Therefore, I conclude that ORI has not shown that SFN2008 was ever published or presented and, as result, it has not been shown that any false reporting of PHS funded research occurred due to that poster.

ORI alleges in ORI Charge 1c, as to the remaining two grant applications, the article, and the two posters, that Respondent used an image that was labeled or described three different ways.

(a.) ORI has made a prima facie showing that there are false images in the materials cited in the ORI Charge.

After careful comparison of the image in the article (NR2010 Figure 5B, ORI Ex. 10 at 5) with the images in the two posters and two grant applications for which Respondent was the PI (ORI Exs. 2, 7, 15, 16), I find that the image in NR2010 Figure 5B is not the same image as that in the posters or the grants. Because I have rejected Runko and his analysis, I am left to examine the images on my own and my findings are based upon recognition or identification of images as a layperson without scientific training. Because the image in NR2010 Figure 5B is different than the images in question in the two grants and the two posters, the images and their descriptions cannot be compared, at least not by a layperson without the scientific knowledge to interpret the content of the images.

Comparing R01 NS064976-01A1 Figure 7 (ORI Ex. 7 at 11) and R01 NS064976-01A2 Figure 7 (ORI Ex. 2 at 5), I find that the images and their labels and descriptions are the same. I find that the same images appear in the posters VA 2009 Figure 3 (ORI Ex. 15) and VA 2010 Figure 3 (ORI Ex. 16) with the same descriptions in both posters and an inconsequential difference in labeling of the images as between the grant applications and the posters. There is, however, a significant difference in the descriptions as between the grant applications and the posters. The descriptions in the grant applications indicate that the image representing the effects of TBI without treatment was based on analysis of cell injury at four hours post-TBI. In the VA posters, it is represented that the TBI (no treatment) slide reflects the amount of neuronal cell injury 48 hours after TBI. Even a layperson can discern the difference between the two descriptions and that difference shows it is more likely than not that one of the descriptions is false. Respondent has not rebutted that at least one description for the images is false. Respondent testified that the description as it appeared in the two grant applications is actually the correct description. Respondent agreed in response to my questioning that the description in the two posters was incorrect. Tr. 813-15. His testimony is un rebutted.

(b.) ORI has made a prima facie showing that some of the materials cited in the ORI Charge were used in applying for PHS funding or in reporting PHS funded research.

The evidence shows it is more likely than not that the description of the images in the VA posters was false. Respondent does not dispute that the VA2009 and VA2010 posters were presented. Therefore, the evidence shows that false materials were used in reporting PHS funded research. Therefore, this element is satisfied.

(c.) ORI has made a prima facie showing that the false images or graphs used in materials cited in the ORI Charge were used in violation of the standard practices for the PHS research community established by the Secretary in 42 C.F.R. pt. 93.

Using images that are false or falsely labeled or described violates the standard practices of the PHS research community.

(d.) ORI has made a prima facie showing that Respondent recklessly used the false images or graphs in the materials cited in the ORI Charge, i.e., without exercising proper care or caution or with disregard or indifference to the risk that the materials were false.

For reasons, already discussed, Respondent recklessly used falsely described images in the VA2009 and VA2010 posters for which he was the lead author.

I conclude based on the evidence of record that it is more likely than not that Respondent committed research misconduct related to the posters VA2009 and VA2010 Figure 3.

I have considered carefully Respondent's arguments that the errors reflected by the charge are simply honest error. Honest error does not negate or rebut the proof of recklessness. Honest error is also not a defense as there is no question that the images were false and whether or not they were false when included in the grant applications and the posters was not even considered by Respondent who admits he simply assumed that others reliably performed research and truthfully reported the results of research.

Accordingly, I conclude that two instances of research misconduct have been proved under ORI Charge 1c.

(5) ORI Charge 1d: Respondent intentionally, knowingly, or recklessly re-used images of smCx as sham-operated, 15 minutes, 4, 24, and 48 hours post-TBI in NR2007-1, R01 NS064590-01, and R01 NS069937-01, Figure 2A-F,

to represent *mild exercise, mild exercise +TBI, strenuous exercise, TBI, and 7 days strenuous exercise followed by TBI treatment in smCx in*

R01 NS065824-01, Figure 4A-F.

ORI Ex. 67 at 22.

The following table lists the various images from the charge, a description of the type of document in which the image appears as that affects what ORI must prove, and the citation to the ORI exhibit where the document and image may be found.

IMAGE	DESCRIPTION	DATE OF DOCUMENT	ORI EXHIBIT
NR2007-1, Fig. 2A-F	José A. Rafols et al., <i>Extent of Nerve Cell Injury in Marmarou's Model Compared to Other Brain Trauma Models</i> , 29 Neurological Research 348, 351 (2007)	2007	ORI Ex. 37 at 4
R01 NS064590-01, Fig. 2A-F	Grant Application, Dore-Duffy PI Alleged by ORI to be correctly described.	3/7/2007	ORI Ex. 38 at 4
R01 NS069937-01, Fig. 2A-F	Grant Application, Dore-Duffy PI Alleged by ORI to be correctly described.	6/5/2009	ORI Ex. 39 at 2
R01 NS065824-01, Fig. 4A-F	Grant Application, Respondent PI	10/1/2008	ORI Ex. 8 at 3

(a.) ORI has made a prima facie showing that there are false images in the materials cited in the ORI Charge.

This charge alleges that the image, which consists of six panels, was falsely described in Respondent's grant application R01 NS065824-01 Figure 4A-F. ORI cites the images in the 2007 Neurological Research article (NR2007-1, ORI Ex. 37 at 4) and Dore-Duffy's two grant applications (R01 NS064590-01 and R01 NS069937-01, Figure 2A-F, ORI Exs. 38 at 4, 39 at 2) as the same image with the correct descriptions. Respondent admitted the image was correctly described in NR2007-1 and in Dore-Duffy's grant applications. ORI Ex. 53 at 76-77; Tr. 816. Respondent admits that the image depicted by Figure 4A-F in his grant application R01 NS065824-01 was inserted erroneously and the description did not match the image. Respondent states that the mistake was discovered, but the grant application was withdrawn due to low probability of funding. ORI Ex. 52 at 13; ORI Ex. 53 at 77-80; Tr. 817. Respondent testified that he had very little to do with the grant application. Tr. 413-15.

(b.) ORI has made a prima facie showing that some of the materials cited in the ORI Charge were used in applying for PHS funding or in reporting PHS funded research.

There is no dispute that Respondent submitted grant application R01 NS065824-01 about October 1, 2008, seeking PHS funds for research. ORI Ex. 8 at 3; ORI Ex. 52 at 13; ORI Ex. 53 at 77-80; Tr. 816-17.

(c.) ORI has made a prima facie showing that the false images or graphs used in materials cited in the ORI Charge were used in violation of the standard practices for the PHS research community established by the Secretary in 42 C.F.R. pt. 93.

Using images that are false or falsely labeled or described violates the standard practices of the PHS research community.

(d.) ORI has made a prima facie showing that Respondent recklessly used the false images or graphs in the materials cited in the ORI Charge, i.e., without exercising proper care or caution or with disregard or indifference to the risk that the materials were false.

I conclude it is more likely than not that Respondent committed research misconduct related to his grant application R01 NS065824-01 Figure 4A-F.

I have considered carefully Respondent's arguments that the errors reflected by the charge are simply honest error. Honest error does not negate or rebut the proof of recklessness. Honest error is also not a defense as there is no question that the image as described was false when inserted in the grant application, and Respondent admits that after submission of the grant application he recognized the falsity. Respondent asserts that he withdrew the grant application, but the regulation clearly applies to applications for PHS funding whether or not granted or withdrawn.

Accordingly, I conclude that one instance of research misconduct has been proved under ORI Charge 1d.

(6) ORI Charge 2: Respondent intentionally, knowingly, or recklessly falsified the reporting of systolic blood pressure curves by re-using and falsely labeling mean arterial pressure measurements to represent treatments with different endothelin receptor antagonists in different numbers of animals.

ORI Charge 2 alleges that Respondent falsely labeled graphs. I have concluded, for reasons already discussed, that it has not been established by a preponderance of the evidence that Respondent falsely labeled any of the images or graphs that are the subject of the ORI charges.

(7) ORI Charge 2a: Respondent intentionally, knowingly, or recklessly re-used a single systolic blood pressure curve to represent

(a) 1.0 mg/kg clazosentan treatment in 3 rats in

R01 NS064976-01, Figure 10A, and

R01 NS064976-01A1 and R01 NS064976-01A2, Figure 13A; and

(b) 20 nmol BQ-123 treatment post-TBI in 4 rats in

NR2010, Figure 4A.

ORI Ex. 67 at 24.

ORI Charge 2a alleges that Respondent used a single systolic blood pressure curve, i.e., a graph, to represent one thing in his grant applications, R01 NS064976-01 Figure 10A, R01 NS064976-01A1 Figure 13A, and R01 NS064976-01A2, Figure 13A, but, something

different was described as being represented by the same graph in the article NR2010 Figure 4a.

The following table lists the various graphs from the charge, a description of the type of document in which the graph appears as that affects what ORI must prove, and the citation to the ORI exhibit where the document and graph may be found.

GRAPHS	DESCRIPTION	DATE OF DOCUMENT	ORI EXHIBIT
R01 NS064976-01, Fig. 10A	Grant Application, Respondent PI	6/2/2008	ORI Ex. 6 at 4
R01 NS064976-01A1, Fig. 13A	Grant Application, Respondent PI	11/17/2008	ORI Ex. 7 at 14
R01 NS064976-01A2, Fig. 13A	Grant application, Respondent PI	3/13/2009	ORI Ex. 2 at 8
NR2010, Fig. 4A	Christian W. Kreipke et al., <i>Differential Effects of Endothelin Receptor A and B Antagonism on Cerebral Hypoperfusion Following Traumatic Brain Injury</i> , 32 Neurological Research 209, 213 (2010)	2010	ORI Ex. 10 at 5

(a.) ORI has made a prima facie showing that there is a falsely described graph in the article NR2010 Figure 4A, as cited in the ORI Charge.

Comparison of the images of graphs in the various documents is not complicated and all are nearly the same except for the description. Respondent pointed out that the graphs are not identical but that is not the basis for the alleged research misconduct. Respondent testified, and his testimony is un rebutted on this point, that the blood pressure curves are accurate, and that was confirmed by Dr. Kaatz's evaluation of the data. Tr. 434. In Respondent's three grant applications, the images of the graphs were labeled to indicate the graphs represented the effect of a certain type of treatment on blood pressure in one group of three rats. ORI Exs. 2 at 8; 6 at 4; 7 at 14. Respondent testified that the graphs were correctly described in the grant applications but not the article. Tr. 817-19. In the article, NR2010 Figure 4A was

described as showing the effect, or lack thereof, of one type of treatment upon mean arterial pressure after TBI in one group of four rats. ORI Ex. 10 at 5.

Respondent testified the article was Rafols'. Respondent testified that Rafols was both the senior author and corresponding author. But Respondent did not deny and ultimately admitted that he was also listed first on the article, but he implied that was by default and he did not actually write the article. Tr. 416-18, 441-43. Respondent also testified that BQ-123 and clazosentan are both endothelin antagonists, that 1.0 milligram per kilogram of clazosentan and 20 nmol BQ-123 are the same dose or quantity, with a slight difference in the compound. He testified that the difference in describing the drugs as being delivered to three rats in one instance and four in the other was simply inadvertent. While Respondent admitted that the labeling in the article was wrong, he asserted it was honest error. Tr. 419-22.

I conclude that the graph in NR2010 Figure 4A was false. But for reasons already discussed, ORI has failed to show that the graphs in the grant applications were false. ORI presented no expert to interpret the graphs who could credibly testify that the descriptions of the graphs were false in the grant applications. There is no evidence that either Runko or Cunningham had the required expertise. Respondent's testimony that the graphs were correctly described in his grant applications is un rebutted. The fact that Respondent admitted that the description of the graph in the article is wrong, gives additional credibility to his un rebutted testimony.

(b.) ORI has made a prima facie showing that some of the materials cited in the ORI Charge were used in applying for PHS funding or in reporting PHS funded research but that showing is rebutted by Respondent's testimony as to the grant applications.

The inconsistency between the descriptions of the graphs in the grant applications and the article makes it more likely than not that at least one of those descriptions is false. Respondent's un rebutted and credible testimony that the descriptions in the grant applications are correct but not the description in the article shows it is more likely than not that the descriptions in the applications seeking PHS funding were accurate while the description in the article reporting PHS funded research was false.

(c.) ORI has made a prima facie showing that the false images or graphs used in materials cited in the ORI Charge were used in violation of the standard practices for the PHS research community established by the Secretary in 42 C.F.R. pt. 93.

Using images that are false or falsely labeled or described violates the standard practices of the PHS research community.

(d.) ORI has made a prima facie showing that Respondent recklessly used the falsely described graph in the article NR2010 Figure 4A, i.e., without exercising proper care or caution or with disregard or indifference to the risk that the description of the graph was false.

I conclude, on the same basis as discussed under ORI Charge 1, that it is more likely than not that Respondent recklessly committed research misconduct related to his article NR2010 Figure 4A. ORI Ex. 10 at 5.

I have considered carefully Respondent's arguments that the error reflected by the charge is simply honest error. Honest error does not negate or rebut the proof of recklessness. Honest error is also not a defense as there is no question that the graph as described was false when inserted in the article.

Accordingly, I conclude that one instance of research misconduct has been proved under ORI Charge 2a.

(8) ORI Charge 2b: Respondent intentionally, knowingly, or recklessly re-used a second systolic blood pressure curve to represent

(a) *1.0 mg/kg clazosentan treatment post-TBI in 3 rats in*

R01 NS064976-01, Figure 10B, and

R01 NS064976-01A1 and R01 NS064976-01A2, Figure 13B, and

in the posters SFN2008, Figure 5, and WB2009, VA2009, and VA2010, Figure 4;

(b) *1.0 mg/kg clazosentan treatment post-TBI in 6 rats in*

NR2011-1, Figure 2; and

(c) *5 nmol BQ-788 treatment post-TBI in 4 rats in*

NR2010, Figure 4B.

ORI Ex. 67 at 25.

The following table lists the various graphs from the charge, a description of the type

of document in which the graphs appear as that affects what ORI must prove, and the citation to the ORI exhibit where the document and graphs may be found.

GRAPHS	DESCRIPTION	DATE OF DOCUMENT	ORI EXHIBIT
R01 NS064976-01, Fig. 10B	Grant Application, Respondent PI	6/2/2008	ORI Ex. 6 at 4
R01 NS064976-01A1, Fig. 13B	Grant Application, Respondent PI	11/17/2008	ORI Ex 7 at 14
R01 NS064976-01A2, Fig. 13B	Grant Application, Respondent PI	3/13/2009	ORI Ex. 2 at 8
SFN2008, Fig. 5	Society for Neuroscience Poster	Undated	ORI Ex. 13
WB2009, Fig. 4	Winter Brain Poster	Undated	ORI Ex. 14
VA2009, Fig. 4	VA Presentation Poster	Undated	ORI Ex. 15
VA2010, Fig. 4	VA Presentation Poster	Undated	ORI Ex. 16
NR2011-1, Fig. 2	Christian W. Kreipke et al., <i>Clazosentan, A Novel Endothelin A Antagonist, Improves Cerebral Blood Flow and Behavior After Traumatic Brain Injury</i> , 33 Neurological Research 208, 211 (2011)	2011	ORI Ex. 11 at 4
NR2010, Fig. 4B	Christian W. Kreipke et al., <i>Differential Effects of Endothelin Receptor A and B Antagonism on Cerebral Hypoperfusion Following Traumatic Brain Injury</i> , 32 Neurological Research 209, 213 (2010)	2010	ORI Ex. 10 at 5

(a.) ORI has made a prima facie showing that there is a falsely described graph in the article NR2010 Figure 4B, as cited in the ORI Charge.

The charge is that Respondent used a graph of systolic blood pressure labeled or described three different ways. ORI does not allege in ORI Charge 2b which label or description is actually false.

Respondent admitted during his August 6, 2012 interview by Runko and Dahlberg, that Figure 4B in NR2010 was wrong. ORI Ex. 53 at 30. Respondent explained during examination at hearing that there was no error as between his grant applications and the VA posters and the NR2011 article. The grant applications described the graph as depicting the effect of 1.0 mg/kg clazosentan treatment post-TBI in 3 rats, but the NR 2011 article described the graph as representing the same therapy post-TBI in 6 rats. Respondent testified that the therapy was applied to two groups of three rats so both descriptions are true, although confusing when one examines the grant applications, posters, and NR 2011 article side by side. Respondent's testimony is unrebutted and is credible given his admission of the error in the NR2010 article. I also note that the descriptions, when considered together, explain that the therapy had no measurable effect on mean arterial pressure in either three or six animals. ORI Exs. 2 at 8; 6 at 4; 7 at 14; 11 at 4.

I conclude it is more probable than not that falsification occurred in the description of Figure 4B in the NR2010 article, but not the grant applications, the VA posters, or the NR2011 article.

I do not consider the posters SFN2008 and WB2009 because ORI has not shown it is more likely than not that they were ever published or presented except by ORI in this proceeding.

(b.) ORI has made a prima facie showing that some of the materials cited in the ORI Charge were used in applying for PHS funding or in reporting PHS funded research.

I find no false material in Respondent's grant applications listed in the charge. I also find no false information related to PHS funded research was reported in the VA posters or the NR2011 article. However, I conclude that there was false reporting related to PHS funded research in the NR2010 article, specifically in the description of Figure 4B. ORI Ex. 10 at 5.

(c.) ORI has made a prima facie showing that the false graphs used in materials cited in the ORI Charge were used in violation of the standard practices for the PHS research community established by the Secretary in 42 C.F.R. pt. 93.

Using images that are false or falsely labeled or described violates the standard practices of the PHS research community.

(d.) ORI has made a prima facie showing that Respondent recklessly used the falsely described graph in the article NR2010 Figure 4B, i.e., without exercising proper care or caution or with disregard or indifference to the risk that the description of the graph was false.

I conclude, on the same basis as discussed under ORI Charge 1, that it is more likely than not that Respondent recklessly committed research misconduct related to the article NR2010 Figure 4B. ORI Ex. 10 at 5.

I have considered carefully Respondent's arguments that the error reflected by the charge is simply honest error. Honest error does not negate or rebut the proof of recklessness. Honest error is also not a defense as there is no question that the graph as described was false when inserted in the article.

Accordingly, I conclude that one instance of research misconduct has been proved under ORI Charge 2b.

(9) ORI Charge 3: Respondent intentionally, knowingly, or recklessly falsified the reporting of cerebral blood flow ("CBF") measurements by re-using and falsely labeling graphs to represent treatments with different endothelin receptor antagonists at various times in different numbers of animals.

ORI Charge 3 alleges that Respondent falsely labeled graphs. I have concluded, for reasons already discussed, that it has not been established by a preponderance of the evidence that Respondent falsely labeled any of the images or graphs that are the subject of the ORI charges.

(10) ORI Charge 3a: Respondent intentionally, knowingly, or recklessly re-used a single graph of CBF in the smCx with 0.1, 1.0, or 10 mg/kg Bosentan administered at 30 minutes post-TBI in 4 animals per group in R01 NS064976-01, Figure 9, to represent

(a) 0.01, 0.1, or 1.0 mg/kg BQ-788 administered at 30 minutes post-TBI in 6 animals per group in

R01 NS064976-01A1 and R01 NS064976-01A2, Figure 5; and

(b) 1, 10, or 20 nmol BQ-788 administered at 24 hours pre-TBI in 6 animals per group in

NR2010, Figure 3A.

ORI Ex. 67 at 26.

The following table lists the various graphs from the charge, a description of the type of documents in which the graphs appear as that affects what ORI must prove, and the citation to the ORI exhibit where the documents and graphs may be found.

GRAPHS	DESCRIPTION	DATE OF DOCUMENT	ORI EXHIBIT
R01 NS064976-01, Fig. 9	Grant Application, Respondent PI Alleged by ORI to be correctly described. ORI Ex. 67 at 26 ¶ 113.	6/2/2008	ORI Ex. 6 at 4
R01 NS064976-01A1, Fig. 5	Grant Application, Respondent PI	11/17/2008	ORI Ex. 7 at 10
R01 NS064976-01A2, Fig. 5	Grant Application, Respondent PI	3/13/2009	ORI Ex. 2 at 4
NR2010, Fig. 3A	Christian W. Kreipke et al., <i>Differential Effects of Endothelin Receptor A and B Antagonism on Cerebral Hypoperfusion Following Traumatic Brain Injury,</i>	2010 (accepted for publication in 1/2009)	ORI Ex. 10 at 4

	32 Neurological Research 209, 212 (2010)		
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(a.) ORI has made a prima facie showing that there are falsely described graphs in the materials cited in the ORI Charge.

ORI Charge 3a alleges generally that Respondent used a graph in two of his grant applications and an article that was labeled differently than Figure 9 in his grant application R01 NS064976-01. ORI reasons that the grant application R01 NS064976-01 was submitted June 2, 2008, before the submission of the two grant applications and the date of acceptance for publication of the article, NR2010 (ORI Ex. 10 at 1 n(unnumbered)), and that is the basis for the charge that the two grants and the article included the falsely described graph. I can readily identify that the graphs are the same with the exception that some are presented in color and some in black and white. It is also apparent that the labeling is different. Respondent explained at hearing that the difference is “just semantics of how it’s displayed as the experimental protocol.” Tr. 423-24. Respondent failed to address why the description of Figure 9 in his application R01 NS064976-01 states that bosentan was administered at 30 minutes post-TBI but the same graph was described as BQ-788 administered at 30 minutes post-TBI in his grant applications R01 NS064976-01A1 Figure 5 and R01 NS064976-01A2 Figure 5 and BQ-788 administered at 24 hours pre-TBI in the article NR2010 Figure 3A. Respondent also failed to explain why the descriptions of the graphs in the two grant applications and the article included different numbers of animals per group tested than what was stated in the description of Figure 9 in his application R01 NS064976-01.

I conclude that the preponderance of the evidence shows that the descriptions of the graphs in Figure 5 of Respondent’s grant applications R01 NS064976-01A1 and R01 NS064976-01A2 and Figure 3A of the article NR2010 are more likely than not false.

(b.) ORI has made a prima facie showing that some of the materials cited in the ORI Charge were used in applying for PHS funding or in reporting PHS funded research.

There is no dispute that R01 NS064976-01A1 and R01 NS064976-01A2 were applications for PHS funded grants filed by Respondent. There is also no dispute that the article NR2010 purported to report the results of PHS funded research.

(c.) ORI has made a prima facie showing that the falsely described graphs used in materials cited in the ORI Charge were used in violation of the standard practices for the PHS research community established by the Secretary in 42 C.F.R. pt. 93.

Using images that are false or falsely labeled or described violates the standard practices of the PHS research community.

(d.) ORI has made a prima facie showing that Respondent recklessly used the falsely described graphs in the materials cited in the ORI Charge, i.e., without exercising proper care or caution or with disregard or indifference to the risk that the materials were false.

I conclude, on the same basis as discussed under ORI Charge 1, that it is more likely than not that Respondent recklessly committed research misconduct related to his grant applications R01 NS064976-01A1 Figure 5 and R01 NS064976-01A2 Figure 5 and the article NR2010 Figure 3A.

I have considered carefully Respondent's arguments that the errors reflected by the charge are simply honest error. Honest error does not negate or rebut the proof of recklessness. Honest error is also not a defense as there is no question that the graphs as described were false when inserted in the grant applications and the article.

Accordingly, I conclude that three instances of research misconduct have been proved under ORI Charge 3a.

(11) ORI Charge 3b: Respondent intentionally, knowingly, or recklessly re-used a second graph of CBF in the smCx and Hipp with 40 nmol BQ-123 administered at 1 hour post-TBI in 4 animals per group in R01 NS064976-01, Figure 6, to represent

(a) 0.01, 0.1, or 1.0 mg/kg BQ-788 administered at 30 minutes post-TBI in 6 animals per group in

R01 NS064976-01A1 and R01 NS064976-01A2, Fig. 5

(b) 1.0 mg/kg clazosentan administered at 30 minutes post-TBI in 6 animals per group in the posters

SFN2008, Figure 6, and WB2009, VA2009, and VA2010, Figure 5;

(c) *1.0 mg/kg clazosentan administered at 2 hours post-TBI in 6 animals per group in*

the poster WC2010, Figure 4; and

(d) *40 nmol BQ-123 administered at 24 hours pre-TBI in 6 animals per group in*

NR2010, Figure 2.

ORI Ex. 67 at 27.

The following table lists the various graphs from the charge, a description of the type of document in which the graphs appear as that affects what ORI must prove, and the citation to the ORI exhibit where the documents and graphs may be found.

GRAPH	DESCRIPTION	DATE OF DOCUMENT	ORI EXHIBIT
R01 NS064976-01, Fig. 6	Grant Application, Respondent PI Alleged by ORI to be correctly described. ORI Ex. 67 at 26 ¶ 118.	6/2/2008	ORI Ex. 6 at 3
R01 NS064976-01A1, Fig. 5	Grant Application, Respondent PI	11/17/2008	OR Ex. 7 at 10
R01 NS064976-01A2, Fig. 5	Grant Application, Respondent PI	3/13/2009	ORI Ex. 2 at 4
SFN2008, Fig. 6	Society For Neuroscience Poster	Undated	ORI Ex. 13
WB2009, Fig. 5	Winter Brain Poster	Undated	ORI Ex. 14
VA2009, Fig. 5	VA Presentation Poster	Undated	ORI Ex. 15
VA2010, Fig. 5	VA Presentation Poster	Undated	ORI Ex. 16
WC2010, Fig. 4	World Congress Poster	Undated	ORI Ex. 17
NR2010, Fig. 2	Christian W. Kreipke et al., <i>Differential Effects of Endothelin Receptor A and B Antagonism on Cerebral Hypoperfusion</i>	2010	ORI Ex. 10 at 3

	<i>Following Traumatic Brain Injury, 32 Neurological Research 209, 211 (2010)</i>		
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(a.) ORI has made a prima facie showing that there are falsely described graphs in the materials cited in the ORI Charge.

ORI alleges in ORI Charge 3b that Respondent falsely described a graph four different ways in two grant applications, five posters, and an article. For reasons already discussed, I have concluded that the evidence does not show it more likely than not that the posters, SFN2008, WB2009, and WC2010, were ever published or presented except by ORI in this case. I have concluded that it has not been shown that the three posters resulted in the reporting of false results of PHS funded research. I do not address those posters further in connection with this charge.

ORI alleges in Charge 3b that Respondent used falsely described graphs in his grant applications R01 NS064976-01A1 and R01 NS064976-01A2, Fig. 5. ORI Ex. 67 at 27. But, ORI does not explain the basis for that charge in the Charge document. ORI Ex. 67 at 27 ¶¶ 118-122. Runko asserts in his declaration that ORI Charge 3b as alleged in the Charge document is in error. Runko provides a revision of the charge in his declaration that does not include the two grant applications, an apparent concession that the allegations regarding the two grant applications are unfounded. ORI Ex. 69 at 5. I conclude that ORI has elected not to proceed upon the allegation of falsely described graphs in Respondent's grant applications.

ORI alleges that Respondent correctly described the graph in his grant application R01 NS064976-01 Figure 6 (ORI Ex. 6 at 3) because that grant application predates the VA2009 and VA2010 posters, and the date the NR2010 article was accepted for publication in January 2009 (ORI Ex. 10 at 1 n(unnumbered)). ORI Ex. 67 at 27 ¶ 118.

I cannot identify graphs in Respondent's grant applications R01 NS064976-01A1 or R01 NS064976-01A2 or the article NR2010 that look like the graph in Figure 6 in Respondent's grant application R01 NS064976-01. Accordingly, I conclude that the evidence does not show falsely described graphs in the two grant applications or the article NR2010 as alleged in ORI Charge 3b.

I can readily identify that the graphs in the two VA posters, VA2009 Figure 5 and VA2010 Figure 5, are the same as the graph in the left panel of Figure 6 in Respondent's grant application R01 NS064976-01. It is also apparent that the descriptions are different in the grant application and the posters. Specifically, in

Figure 6 of the grant application, the graph is labeled as reflecting the effect of BQ-123 administered at 1 hour post-TBI in four animals but the graph in Figure 5 of both VA posters is described as reflecting the effect of clazosentan administered 30 minutes after TBI in six rats. Even if I accept Respondent's assertion that BQ-123 and clazosentan are essentially the same chemical compound, Respondent failed to explain the difference in the number of rats upon which the experiment was conducted and the difference in the timing of the administration of the chemical. Tr. 424-25. I conclude that the preponderance of the evidence shows that the descriptions of Figure 5 in VA2009 and VA2010 were false.

(b.) ORI has made a prima facie showing that some of the materials cited in the ORI Charge were used in applying for PHS funding or in reporting PHS funded research.

There is no dispute that the VA posters, VA2009 and VA2010, were actually presented resulting in the false reporting PHS funded research results.

(c.) ORI has made a prima facie showing that the falsely described graphs used in materials cited in the ORI Charge were used in violation of the standard practices for the PHS research community established by the Secretary in 42 C.F.R. pt. 93.

Using images that are false or falsely labeled or described violates the standard practices of the PHS research community.

(d.) ORI has made a prima facie showing that Respondent recklessly used the falsely described graphs in the VA Posters, VA2009 and VA2010 Figure 5, i.e., without exercising proper care or caution or with disregard or indifference to the risk that the materials were false.

I conclude, on the same basis as discussed under ORI Charge 1, that it is more likely than not that Respondent recklessly committed research misconduct related to the VA posters, VA2009 and VA2010 Figure 5, which resulted in the false reporting of PHS funded research results.

I have considered carefully Respondent's arguments that the errors reflected by the charge are simply honest error. Honest error does not negate or rebut the proof of recklessness. Honest error is also not a defense as there is no question that the graphs as described were false when inserted in the posters.

Accordingly, I conclude that two instances of research misconduct have been proved under ORI Charge 3b.

(12) ORI Charge 4: Respondent intentionally, knowingly, or recklessly falsified the reporting of Western blots by re-using and falsely labeling blots to represent the expression of different proteins at various times from different brain regions in different numbers of animals that were subjected to different treatments - TBI, exercise, and/or administration with endothelin-1.

ORI Charge 4 alleges that Respondent falsely labeled images of western blots. I have concluded, for reasons already discussed, that it has not been established by a preponderance of the evidence that Respondent falsely labeled any of the images or graphs that are the subject of the ORI charges.

(13) ORI Charge 4a: Respondent intentionally, knowingly, or recklessly re-used a Western blot of vascular endothelial growth factor receptor-2 (“VEGFR2”) protein expression in smCx in control or following exercise preconditioning and trauma in 3 animals per group in the grant applications R01 NS064590-01 and R01 NS069937-01, Figure 8E, to represent

(a) *vascular endothelial growth factor (“VEGF”) protein expression in the Hipp in control or after mild exercise at 24 or 48 hours or 7 days prior to TBI in 6 animals per group in*

R01 NS065824-01, Figure 1, panel 3;

(b) *endothelin receptor B (“ETrB”) protein expression in smCx vascular tissue in control or at 4, 24, or 48 hours post-TBI in*

R01 NS064976-01A1 and R01 NS064976-01A2, Figure 2B;

(c) *endothelin receptor A (“ETrA”) protein expression in smCx tissue in control and with 200pg endothelin-1 (“ET-1”) administration at 4 hours in 3 animals per group in*

R01 NS039860-09A2, Figure 3B; and

(d) *ETrB* protein expression in capillaries isolated from cortical brain tissue in control or TBI animals at post-impact 4, 24, or 48 hours in 3 animals per group in

NR2011-2, Figure 6B, and

CBF2013, page 31, Figure 2.2b.

ORI Ex. 67 at 28.

The following table lists the images of western blots from ORI Charge 4a, a description of the type of document in which the images appeared as that affects what ORI must prove, and the citation to the ORI exhibit or Court exhibit where the documents and images may be found.

IMAGE	DESCRIPTION	DATE OF DOCUMENT	ORI EXHIBIT
R01 NS064590-01, Fig. 8E	Grant Application, Dore-Duffy PI ORI alleges image is correctly described.	3/7/2008	ORI Ex. 38 at 7
R01 NS069937-01, Fig. 8E	Grant Application, Dore-Duffy PI ORI alleges image is correctly described.	6/5/2009	ORI Ex. 39 at 5
R01 NS065824-01, Fig. 1 3d Panel (Image of black bars)	Grant Application, Respondent PI	10/1/2008	ORI Ex. 8 at 2
R01 NS064976-01A1, Fig. 2B (Image of black bars)	Grant Application, Respondent PI	11/17/2008	ORI Ex. 7 at 9
R01 NS064976-01A2, Fig. 2B (Image of black bars)	Grant Application, Respondent PI	3/13/2009	ORI Ex. 2 at 3
R01 NS039860-09A2, Fig. 3B (Image of black bars)	Grant Application, Rafols PI	6/29/2009	ORI Ex. 5 at 3
NR2011-2, Fig. 6B (Image of black bars)	Paula Dore-Duffy et al., <i>Pericyte-Mediated Vasoconstriction</i>	2011	ORI Ex. 12 at 6

	<i>Underlies TBI-induced Hypoperfusion</i> , 33 Neurological Research 176, 181 (2011)		
CBF2013, Fig. 2.2b in ch. 2 at 31 (Image of black bars)	Justin Graves et al., <i>Situating Cerebral Blood Flow in the Pathotrajjectory of Head Trauma</i> , in <u>Cerebral Blood Flow, Metabolism, and Head Trauma</u> , ch. 2, at 31 (Christian W. Kreipke & Jose A. Rafols eds., 2013)	2013	ORI Ex. 18 at 5 (Extract of Book); Ct. Ex. 1 at 22 (DAB E-File Item # 49a) (Complete Book)

(a.) ORI has made a prima facie showing that there are false images in the materials cited in the ORI Charge.

ORI Charge 4a alleges falsely labeled or described images in the grant application R01 NS039860-09A2 for which Rafols was the PI; the article NR2011-2 for which Dore-Duffy was the first listed author; and Chapter 2 of the book CBF2013 for which J. Graves was the first listed author. As previously discussed, based on the evidence presented by ORI, I am unwilling to infer in this case that Respondent was liable for research misconduct for a grant application, poster, article, or book for which he was not the PI or first listed author. ORI has simply failed to establish by a preponderance of the evidence that Respondent caused or was liable for research misconduct for any grant application, article, or book for which he was not the PI or first listed author.

Thus, under ORI Charge 4a, it remains to be determined whether Respondent is liable for falsely described images in his three grant applications, specifically R01 NS065824-01 Figure 1 Panel 3, R01 NS064976-01A1 Figure 2B, and R01 NS064976-01A2 Figure 2B.

ORI alleges that the western blot image in question was correctly labeled in Dore-Duffy's grant applications, R01 NS064590-01 Figure 8E and R01 NS069937-01 Figure 8E. ORI Ex. 67 at 28-29 ¶¶ 123-28. ORI does not specifically allege that the images were correctly labeled but that appears to be the gist of ORI Charge 4a as ORI alleges that the same western blot image was falsely labeled in Respondent's three grant applications. ORI Ex. 67 at 29-30 ¶¶ 134, 136-38. ORI presented no expert witness qualified to testify whether the description of the western blot images in Dore-Duffy's grant application was correct or not. The ORI theory seems to be that one of the Dore-Duffy grant applications predated Respondent's grant applications and the descriptions in the Dore-Duffy grant

applications were consistent, so therefore, they must be accurate. However, ORI also argues that Respondent provided the images and their descriptions to Dore-Duffy for use in her grants. Given ORI's opinion that Respondent has no credibility, and Dore-Duffy's limited involvement in her own grant applications, it is difficult to understand how ORI concludes that the descriptions of the western blot images in the Dore-Duffy grant applications were correct. I cannot conclude based on the record before me that it is more likely than not that the images in the Dore-Duffy grant applications are correctly described and I give that evidence little weight.

I can, however, compare the images in Respondent's three grant applications. In grant application R01 NS065824-01 Figure 1, panel 3 (ORI Ex. 8 at 2), the image is described as a western blot analysis pre-TBI of tissue from the hippocampus. But, in grant applications R01 NS064976-01A1 Figure 2B (ORI Ex. 7 at 9) and R01 NS064976-01A2 Figure 2B (ORI Ex. 2 at 3), the image is described to reflect western blot analysis post-TBI of tissue from the sensorimotor cortex. The two very different descriptions for the same image are obvious to a layperson. It is more likely than not that one of the two inconsistent descriptions for the same image is false. Respondent has failed to explain the inconsistency. Because ORI has not specifically proven which description is false or that both are false, I conclude that only one instance of research misconduct occurred as I cannot determine that the descriptions used in grant applications R01 NS064976-01A1 Figure 2B (ORI Ex. 7 at 9) and R01 NS064976-01A2 Figure 2B (ORI Ex. 2 at 3) are, in fact, false.

(b.) ORI has made a prima facie showing that some of the materials cited in the ORI Charge were used in applying for PHS funding or in reporting PHS funded research.

There is no dispute that R01 NS065824-01,⁴⁷ R01 NS064976-01A1, and R01 NS064976-01A2, are Respondent's grant applications to NIH for PHS funding.

⁴⁷ Although this grant application may have been withdrawn, I conclude that is no defense as 42 C.F.R. pt. 93 specifically applies to applications and not just applications that are granted. 42 C.F.R. § 93.102(b)(1)(i).

(c.) ORI has made a prima facie showing that the false images or graphs used in materials cited in the ORI Charge were used in violation of the standard practices for the PHS research community established by the Secretary in 42 C.F.R. pt. 93.

Using images that are false or falsely labeled or described violates the standard practices of the PHS research community.

(d.) ORI has made a prima facie showing that Respondent recklessly used the falsely described images in his three grant applications cited in the ORI Charge, i.e., without exercising proper care or caution or with disregard or indifference to the risk that the materials were false.

I conclude, on the same basis as discussed under ORI Charge 1, that it is more likely than not that Respondent recklessly committed research misconduct related to one of the descriptions of western blot images in his grant applications R01 NS065824-01, R01 NS064976-01A1, and R01 NS064976-01A2.

I have considered carefully Respondent's arguments that the errors reflected by the charges are simply honest error. Honest error does not negate or rebut the proof of recklessness. Honest error is also not a defense as there is no question that the one of the images as described was false when inserted in one of the grant applications.

Accordingly, I conclude that one instance of research misconduct has been proved under ORI Charge 4a.

(14) ORI Charge 4b: Respondent intentionally, knowingly, or recklessly re-used a Western blot of VEGF protein expression in the Hipp in control or after strenuous exercise at 24 or 48 hours or 7 days prior to TBI in 6 animals per group in R01 NS065824-01, Figure 1, Panel 4 to represent

(a) *ETrA* protein expression in smCx vascular tissue in control or at 4, 24, or 48 hours post-TBI in

R01 NS064976-01A1 and R01 NS064976-01A2, Figure 2A;

(b) *ETrA* protein expression in smCx tissue in control and 4 hours post-TBI in 3 animals per group in

R01-NS039860-09A2, Figure 3A; and

(c) *ETrA* protein expression in capillaries isolated from control or TBI animals at post-impact 4, 24, or 48 hours in 3 animals per group in

NR2011-2, Figure 6A, and

CBF2013, page 31, Figure 2.2a.

ORI Ex. 67 at 30-31.

The following table lists the various images from the charge, a description of the type of document in which the images appear as that affects what ORI must prove, and the citation to the ORI exhibit where the documents and images may be found.

IMAGE	DESCRIPTION	DATE OF DOCUMENT	ORI EXHIBIT
R01 NS065824-01, Fig. 1, 4th Panel	Grant Application, Respondent PI	10/1/2008	ORI Ex. 8 at 2
R01 NS064976-01A1, Fig. 2A	Grant Application, Respondent PI	11/17/2008	ORI Ex. 7 at 9
R01 NS064976-01A2, Fig. 2A	Grant Application, Respondent PI	3/13/2009	ORI Ex. 2 at 3
R01 NS039860-09A2, Fig. 3A	Grant Application, Rafols PI	6/29/2009	ORI Ex. 5 at 3
NR2011-2, Fig. 6A	Paula Dore-Duffy et al., <i>Pericyte-Mediated Vasoconstriction Underlies TBI-induced Hypoperfusion</i> , 33 Neurological Research 176, 181 (2011)	2011	ORI Ex. 12 at 6
CBF2013, Fig. 2.2a in ch. 2 at 31	Justin Graves, et al., <i>Situating Cerebral Blood Flow in the Pathotrajjectory of Head Trauma, in Cerebral Blood Flow, Metabolism, and Head Trauma</i> , ch. 2, at 31	2013	ORI Ex. 18 at 5 (Extract of Book); Ct. Ex. 1 at 21 (DAB E-File Item # 49a) (Complete Book)

	(Christian W. Kreipke & Jose A. Rafols eds., 2013)		
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(a.) ORI has made a prima facie showing that there are false images in the materials cited in the ORI Charge.

ORI Charge 4b alleges that Respondent used an image of a western blot from his grant application, R01 NS065824-01 Figure 1, 4th Panel, falsely labeling the image in two of his own subsequent grant applications, a grant application of Rafols, an article for which Dore-Duffy was the first listed author, and in CBF2013, chapter 2, for which Graves was the first listed author. ORI does not specifically allege that the image of the western blot analysis was correct in R01 NS065824-01 Figure 1, 4th Panel. But ORI alleges that image first appeared in R01 NS065824-01 Figure 1, 4th Panel, and the image appeared with different descriptions in subsequent grant applications, an article, and a book. ORI Ex. 67 at 31 ¶ 141-53. ORI presented no witness qualified as an expert who could credibly opine as to which images were correctly labeled.

As previously discussed, based on the evidence presented by ORI, I am unwilling to infer in this case that Respondent was liable for research misconduct for a grant application, poster, article, or book for which he was not the PI or first listed author. ORI has simply failed to establish by a preponderance of the evidence that Respondent caused or was liable for research misconduct for any grant application, article, or book for which he was not the PI or first listed author.

Thus, under ORI Charge 4b, it remains to be determined whether Respondent is liable for falsely described images in his grant applications, specifically R01 NS064976-01A1 Figure 2A (ORI Ex. 7 at 9) and R01 NS064976-01A2 Figure 2A (ORI Ex. 2 at 3).

The focus of this charge appears in all three grant applications to be a photographic image of three (or possibly four) black smudges, the second from the left being darker and more mushroom shaped and the one on the far right appearing slightly thicker and darker than the others. A layperson can identify that the image in question is the same in all three grant applications. In Respondent's grant application R01 NS065824-01 Figure 1, the description indicates that the image represents western blot analysis of a hippocampus sample from an animal subject to strenuous exercise followed by TBI. ORI Ex. 8 at 2. However, in Respondent's grant applications R01 NS064976-01A1 Figure 2A (ORI Ex. 7 at 9) and R01 NS064976-01A2 Figure 2A (ORI Ex. 2 at 3), the same image is described as the result of a western blot analysis of a sample from the sensorimotor cortex of an animal post-TBI. I conclude that it is more likely than not that one of the two descriptions is false. Respondent has not credibly explained the difference. I further conclude that the images as described in the two later grant

applications are more likely than not the false descriptions. Accordingly, I conclude that ORI has proved two instances of research misconduct under ORI Charge 4b.

(b.) ORI has made a prima facie showing that some of the materials cited in the ORI Charge were used in applying for PHS funding or in reporting PHS funded research.

There is no dispute that R01 NS064976-01A1 and R01 NS064976-01A2 were Respondent's applications to NIH for PHS grant funds.

(c.) ORI has made a prima facie showing that the false images or graphs used in materials cited in the ORI Charge were used in violation of the standard practices for the PHS research community established by the Secretary in 42 C.F.R. pt. 93.

Using images that are false or falsely labeled or described violates the standard practices of the PHS research community.

(d.) ORI has made a prima facie showing that Respondent recklessly used the false images in his two grant applications cited in the ORI Charge, i.e., without exercising proper care or caution or with disregard or indifference to the risk that the materials were false.

I conclude, on the same basis as discussed under ORI Charge 1, that it is more likely than not that Respondent recklessly committed research misconduct related to the false descriptions of the western blot images in his grant applications, specifically R01 NS064976-01A1 Figure 2A (ORI Ex. 7 at 9) and R01 NS064976-01A2 Figure 2A (ORI Ex. 2 at 3)

I have considered carefully Respondent's arguments that the errors reflected by the charges in this case are simply honest error. Honest error does not negate or rebut the proof of recklessness. Honest error is also not a defense as there is no question that the image as described was false when inserted in the grant applications.

Accordingly, I conclude that two instances of research misconduct have been proved under ORI Charge 4b.

(15) ORI Charge 4c: Respondent intentionally, knowingly, or recklessly re-used Western blots of angiopoietin-1 (“Ang1”) and angiopoietin-2 (“Ang2”) protein expression of immunoprecipitated whole cell lysates isolated from C57BL/6 mice cortex-isolated microvessels in controls or at 6 or 12 hours or 1 or 7 days following exposure to hypoxia, in AE2006, Figure 2, panels 2 and 3, and the grant applications R01 NS064590-01 and R01 NS069937-01, Figure 11, panels 2 and 3,

to represent *Hypoxia inducible factor-1 α* (“HIF-1 α ”) protein expression in the Hipp of control animals or after mild exercise (“ME”) or strenuous exercise (“SE”) at 12, 24, or 48 hours or 7 days prior to TBI, in 6 animals per group, in

R01 NS065824-01, Figure 1, panels 1 and 2.

ORI Ex. 67 at 32.

The following table lists the images of western blots from the charge, a description of the type of document in which the images appear as that affects what ORI must prove, and the citation to the ORI exhibit where the documents and images may be found.

IMAGE	DESCRIPTION	DATE OF DOCUMENT	ORI EXHIBIT
AE2006, Fig. 2, Panels 2 (Ang1) & 3 (Ang2)	Joseph C. LaManna et al. <i>Is Cyclooxygenase-2 (Cox-2) a Major Component of the Mechanism Responsible for Microvascular Remodeling in the Brain? in Advances in Experimental Medicine and Biology, ch. 47 at 300 (2006)</i> ORI asserts image is correctly labeled.	2006 (ORI Ex. 67 at 32 n.19)	ORI Ex. 35 at 4
R01 NS064590-01, Fig. 11 Panels 2 (Ang1) & 3 (Ang2)	Grant Application, Dore-Duffy PI	3/7/2008	ORI Ex. 38 at 8

	ORI asserts images are correctly labeled.		
R01 NS069937-01, Fig. 11 Panels 2 (Ang1) & 3 (Ang2)	Grant Application, Dore-Duffy PI. ORI asserts images are correctly labeled?	6/5/2009	ORI Ex. 39 at 6
R01 NS065824-01, Fig. 1 Panels 1(me+TBI/HIF-1 α) & 2 (se+TBI/HIF-1 α)	Grant Application, Respondent PI	10/01/2008	ORI Ex. 8 at 2

(a.) ORI has failed to make a prima facie showing that Respondent used falsely described images in his grant application R01 NS065824-01.

(b.) ORI has failed to make a prima facie showing of research misconduct related to Respondent's grant application R01 NS065824-01.

ORI Charge 4c alleges that Respondent used images of western blot analysis that match western blot images from the LaManna book chapter (AE2006) and the two Dore-Duffy grant applications, and falsely described them in Respondent's grant application R01 NS065824-01 Figure 1 Panels 1 and 2.

ORI offered no expert competent to testify as to what the images in question actually represent or whether any of the descriptions at issue are correct or incorrect. A layperson can identify the images as being very similar in appearance, but it is not possible to determine that they are more likely than not the same absent some scientific expertise. It is also possible to determine as a layperson that the descriptions that appear in the LaManna book chapter and Dore-Duffy's grant applications are practically the same and the description in Respondent's grant application is different. Respondent has not admitted that the description in his grant application is the erroneous description. ORI argues in briefing that the book, for which I have no evidence of a copyright date, and Dore-Duffy's grant application R01 NS064590-01 preceded Respondent's grant application, with the implication being that the earliest descriptions must be correct. ORI Br. at 8-9. However, I find the timing of the publication of the book and the submission of the grant application insufficient evidence standing alone to allow me to infer that the description in Respondent's grant application is incorrect or false. ORI's reliance upon Runko's analysis is also misplaced as the analysis is not credible for the reasons already discussed.

Accordingly, I conclude that ORI has failed to make a prima facie showing of any research misconduct under ORI Charge 4c.

(16) ORI Charge 4d: Respondent intentionally, knowingly, or recklessly re-used a Western blot of HIF-1 α protein expression in mice and rats under normobaric and hypobaric hypoxia conditions after 24 hours, in the grant applications R01 NS064590-01 and R01 NS069937-01, Figure 10, panel 1,

to represent Caspase-3 protein expression in the smCx of animals subjected to TBI, SE, SE+TBI, or ME+TBI, in 6 animals per group, in

R01 NS065824-01, Figure 5.

ORI Ex. 67 at 34.

The following table lists the various images of western blot analysis from the charge, a description of the type of document in which the image appears as that affects what ORI must prove, and the citation to the ORI exhibit where the document and image may be found.

IMAGE	DESCRIPTION	DATE OF DOCUMENT	ORI EXHIBIT
R01 NS064590-01, Fig. 10, Far-right image, Panel 1	Grant Application, Dore-Duffy PI	3/7/2008	ORI Ex. 38 at 8
R0 NS069937-01, Fig. 10, Far-right image, Panel 1	Grant Application, Dore-Duffy PI	6/5/2009	ORI Ex. 39 at 6
R01 NS065824-01, Fig. 5	Grant Application, Respondent PI	10/1/2008	ORI Ex. 8 at 4

(a.) ORI has failed to make a prima facie showing that Respondent used falsely described images in his grant application R01 NS065824-01.

(b.) ORI has failed to make a prima facie showing of research misconduct related to Respondent's grant application R01 NS065824-01.

ORI Charge 4d, similarly to ORI Charge 4c, alleges that images described in the two Dore-Duffy grant applications are the same and the description of the image in Respondent's grant application is different.

ORI offered no expert competent to testify as to what the images in question actually represent or whether any of the descriptions at issue are correct or incorrect. A layperson can identify the images as being very similar in appearance, but it is not possible to determine that they are more likely than not the same absent some scientific expertise. It is also possible to determine as a layperson that the descriptions in Dore-Duffy's grant applications are the same and the description in Respondent's grant application is different. Respondent has not admitted that the description in his grant application is the erroneous description. ORI argues in briefing that Dore-Duffy's grant application R01 NS064590-01 preceded Respondent's grant application, with the implication being that the earlier description in the Dore-Duffy grant application R01 NS064590-01 must be correct. ORI Br. at 9; ORI Reply at 7-8. However, I find the timing of the submission of the grant applications insufficient evidence standing alone to allow me to infer that the description in Respondent's grant application is incorrect or false. ORI's reliance upon Runko's analysis is also misplaced as the analysis is not credible for the reasons already discussed.

Accordingly, I conclude that ORI has failed to make a prima facie showing of any research misconduct under ORI Charge 4d.

(17) ORI Charge 5: Respondent intentionally, knowingly, or recklessly falsified the reporting of immunofluorescent labeling of lectin by re-using and falsely labeling an image that represented the controls of male Sprague-Dawley rats not subjected to TBI in MR2006, Figure 4B,

to represent the *smCx* of animals subjected to strenuous exercise prior to TBI

in R01 NS065824-01, Figure 2C.

ORI Ex. 67 at 35.

The following table lists the image from the charge, a description of the type of document in which the image appears as that affects what ORI must prove, and the citation to the ORI exhibit where the document and image may be found.

IMAGE	DESCRIPTION	DATE OF DOCUMENT	ORI EXHIBIT
MR2006, Fig. 4B	Christian W. Kreipke et al., <i>Calponin and Caldesmon Cellular Domains in Reacting</i>	2006	ORI Ex. 36 at 6

	<i>Microvessels Following Traumatic Brain Injury</i> , 71 Microvascular Research 197, 202 (2006)		
R01 NS065824-01, Fig. 2C	Grant Application, Respondent PI	10/1/2008	ORI Ex. 8 at 2

(a.) ORI has made a prima facie showing that there is a falsely described image in Respondent's grant application, specifically R01 NS065824-01 Figure 2C.

Charge 5 is that Respondent used a Fluoro-Jade image from his article MR2006, specifically figure 4B, with a false description in his grant application R01 NS065824-01, Fig. 2C. After considerable study, I am unable as a layperson to determine that the image described as MR2006 Figure 4B is the same image as Figure 2C in Respondent's grant application R01 NS065824-01. Respondent agreed at hearing that he was involved in preparing the article MR2006 but he did not recall which, if any, of the figures or images he added. Tr. 521-22. However, Respondent admitted in response to my questioning that the label for the image in his grant was incorrect, but he testified the description was created by Dore-Duffy. Tr. 824-26.

(b.) ORI has made a prima facie showing that some of the materials cited in the ORI Charge were used in applying for PHS funding or in reporting PHS funded research.

There is no dispute that R01 NS065824-01 is Respondent's grant application to NIH for PHS funding of research.

(c.) ORI has made a prima facie showing that the falsely described image Figure 2C used in Respondent's grant application R01 NS065824-01 was used in violation of the standard practices for the PHS research community established by the Secretary in 42 C.F.R. pt. 93.

Using images that are false or falsely labeled or described violates the standard practices of the PHS research community.

(d.) ORI has made a prima facie showing that Respondent recklessly used the falsely described image Figure 2C in his grant application R01 NS065824-01, i.e., without exercising proper care or caution or with disregard or indifference to the risk that the materials were false.

I conclude, on the same basis as discussed under ORI Charge 1, that it is more likely than not that Respondent recklessly committed research misconduct related to his grant application, specifically R01 NS065824-01 Figure 2C.

I have considered carefully Respondent's arguments that the error reflected by the charge is simply honest error. Honest error does not negate or rebut the proof of recklessness. Honest error is also not a defense as there is no question that the graph as described was false when inserted in the grant application.

Accordingly, I conclude that one instance of research misconduct has been proved under ORI Charge 5.

4. Administrative actions proposed by ORI are unreasonable and the following administrative actions are reasonable on the facts of this case.

Pursuant to 42 C.F.R. § 93.517(a), I am required to conduct an in-person hearing to decide if research misconduct was committed by the Respondent and if the administrative actions proposed by ORI, including debarment or suspension, are appropriate. How I am to determine the appropriateness of the administrative actions is not specified in the regulations. However, I am bound by all federal statutes and regulations, Secretarial delegations of authority, and applicable HHS policies. 42 C.F.R. § 93.506(a), (c). I conclude that in judging the appropriateness of proposed administrative actions I must comply with the same regulations that bound ORI when proposing administrative actions. Authorized administrative actions are established by 42 C.F.R. § 93.407. Authorized mitigating and aggravating factors that may be considered when setting proposed administrative actions are established by 42 C.F.R. § 93.408.

Authorized administrative actions include but are not limited to:

- (1) Clarification, correction, or retraction of the research record.
- (2) Letters of reprimand.

- (3) Imposition of special certification or assurance requirements to ensure compliance with applicable regulations or terms of PHS grants, contracts, or cooperative agreements.
- (4) Suspension or termination of a PHS grant, contract, or cooperative agreement.
- (5) Restriction on specific activities or expenditures under an active PHS grant, contract, or cooperative agreement.
- (6) Special review of all requests for PHS funding.
- (7) Imposition of supervision requirements on a PHS grant, contract, or cooperative agreement.
- (8) Certification of attribution or authenticity in all requests for support and reports to the PHS.
- (9) No participation in any advisory capacity to the PHS.
- (10) Adverse personnel action if the respondent is a Federal employee, in compliance with relevant Federal personnel policies and laws.
- (11) Suspension or debarment under 45 CFR Part 76, 48 CFR Subparts 9.4 and 309.4, or both.

42 C.F.R. § 93.407(a).

According to 42 C.F.R. § 93.408:

The purpose of HHS administrative actions is remedial. The appropriate administrative action is commensurate with the seriousness of the misconduct, and the need to protect the health and safety of the public, promote the integrity of the PHS supported research and research process, and conserve public funds. HHS considers aggravating and mitigating factors in determining appropriate HHS administrative actions and their terms. HHS may consider other factors as appropriate in each case.

Following is the non-exclusive list of mitigating and aggravating factors:

- (a) Knowing, intentional, or reckless. Were the respondent's actions knowing or intentional or was the conduct reckless?
- (b) Pattern. Was the research misconduct an isolated event or part of a continuing or prior pattern of dishonest conduct?
- (c) Impact. Did the misconduct have significant impact on the proposed or reported research record, research subjects, other researchers, institutions, or the public health or welfare?
- (d) Acceptance of responsibility. Has the respondent accepted responsibility for the misconduct by –
 - (1) Admitting the conduct;
 - (2) Cooperating with the research misconduct proceedings;
 - (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.
- (e) Failure to accept responsibility. Does the respondent blame others rather than accepting responsibility for the actions?
- (f) Retaliation. Did the respondent retaliate against complainants, witnesses, committee members, or other persons?
- (g) Present responsibility. Is the respondent presently responsible to conduct PHS supported research?
- (h) Other factors. Other factors appropriate to the circumstances of a particular case.

42 C.F.R. § 93.408.

In this case, ORI's proposed administrative actions are debarment for ten years from eligibility for any contracting or subcontracting with any agency of the United States; debarment for ten years from eligibility for, or involvement in, non-procurement programs of the United States, i.e., "covered transactions;" prohibition from serving in any advisory capacity to PHS, including but not limited to, any PHS advisory committee, board, or peer review committee, or as a consultant for ten years; and the retraction of three articles published in *Neurological Research*, in accordance with 42 C.F.R. § 93.411(b). ORI Ex. 67 at 2-3, 39.

ORI notified Respondent by letter dated February 10, 2016, that it found Respondent engaged in research misconduct and proposed administrative actions. ORI Ex. 67.

ORI proposed administrative actions including the retraction of three articles. ORI Ex. 67 at 3, 39. However, the evidence shows that retraction has already occurred. ORI Ex. 74 reflects that on February 23, 2017, during the pendency of this case, *Neurological Research* issued a statement of retraction covering the three articles ORI proposed for retraction. Pursuant to 42 C.F.R. § 93.411(b), a notice of required correction or retraction was not to be sent to journals until a final HHS action results in settlement or research misconduct findings. HHS action is not final on charges of research misconduct until 30 days after the issuance of my recommended decision if the Assistant Secretary for Health does not notify the parties of an intention to review my recommended decision within that 30-day period; or until the Assistant Secretary issues a decision modifying or rejecting my recommended decision, in whole or in part, in which case that decision is the final HHS decision. Except, if a debarment or suspension is recommended, the decision of the debarring official is the final HHS decision on those administrative actions. 42 C.F.R. § 93.523(b). Therefore, notice to *Neurological Research* by ORI or HHS to retract the three articles would have been inconsistent with 42 C.F.R. § 93.411(b). However, the notice of retraction indicates that the retractions were likely at the behest of WSU rather than ORI or HHS. ORI Ex. 74. Whether or not WSU had the authority to request or direct retraction of the three articles before a HHS final decision on research misconduct, is not an issue that I need to analyze further. Even if I conclude that the retraction was in violation of the Secretary's regulations, I find no authority to fashion any equitable remedy for Respondent. 42 C.F.R. § 93.506.

The non-exclusive list of aggravating and mitigating factors that ORI is authorized to consider is found at 42 C.F.R. § 93.408. ORI's evaluation of the aggravating and mitigating circumstances is set forth in ORI Ex. 67 at 37-38. Based on my comparison of the aggravating and mitigating circumstances ORI considered to the list in 42 C.F.R. § 93.408, I conclude that ORI did not consider circumstances it was not authorized to consider or that I may not consider. I find nothing in the regulations or the applicable statutes that suggests that I am not to exercise de novo review on aggravating and mitigating factors or that I must defer in any respect to the recommendation of ORI. The regulation is very clear that I am to provide de novo review of the "ORI findings of

research misconduct and the proposed HHS administrative actions.” 42 C.F.R. § 93.517(b).

Nevertheless, I recommend that the duration of the administrative actions in this case be reduced to five years based on the following:

(1) ORI determined that there were 64 instances of research misconduct but ORI has only proven 23 instances before me by a preponderance of the evidence, specifically three instances under ORI Charge 1a, six instances under ORI Charge 1b, two instances under ORI Charge 1c, one instance under ORI Charge 1d, one instance under ORI Charge 2a, one instance under ORI Charge 2b, three instances under ORI Charge 3a, two instances under ORI Charge 3b, one instance under ORI Charge 4a, two instances under ORI Charge 4b, no instances under ORI Charges 4c and 4d, and one instance under ORI Charge 5. Instances of research misconduct proved by ORI are related to Respondent’s grant applications and published articles and posters for which he was the first-listed author.

(2) ORI failed to prove by a preponderance of the evidence that Respondent actually created any false images or graphs or their labels or descriptions. I have found by a preponderance of the evidence that Respondent recklessly committed research misconduct. ORI did not prove its allegations that Respondent committed research misconduct knowingly or intentionally, which should be viewed as the more egregious mental states. Committing research misconduct recklessly places both the scientific record and PHS funds at risk just like intentional or knowing misconduct. But the remedial purpose of an administrative action may arguably be accomplished more expediently in the case of reckless behavior than in the case of knowing or intentional behavior. I conclude that a lesser period of adverse administrative action is thus justifiable in the Respondent’s case.

(3) ORI considered that Respondent was found to have committed research misconduct by the VA. Because the list of aggravating and mitigating factors in 42 C.F.R. § 93.408 is not exhaustive, ORI is not prohibited from considering this fact as aggravating. There is no dispute that the VA found Respondent engaged in research misconduct, though Respondent may dispute the VA determination. I conclude it is appropriate to consider that the VA found that Respondent engaged in research misconduct.

(4) ORI also considered as aggravating that Respondent did not simply admit he committed research misconduct but chose to exercise his regulatory due process rights to challenge the allegations of research misconduct; he filed grievances against his employer, and he sought and obtained at least briefly in state court a protective order. The regulation is drafted so broadly that it may not be said that

any of these considerations are prohibited. However, I am reticent to recommend that one be penalized for exercising rights available under federal or state statutes, regulations, or constitutions. Respondent has the right to contest ORI research misconduct findings and HHS administrative actions. 42 C.F.R. §§ 93.500(b), 93.501. Throughout the course of the proceeding before me, Respondent has not appeared to attempt to obstruct the process or evade responsibility. Respondent did not have to testify at hearing but chose to do so. Although some of Respondent's responses may have seemed evasive during the hearing, I have no evidence that Respondent violated his oath. I also note that Respondent's testimony may have seemed evasive at times or less than straightforward due to his years of education and work in science, which made communication with lay people participating in the hearing more difficult. The bottom line is that Respondent merely sought his day in court to mount his defense to charges of research misconduct, the majority of which I have concluded ORI was unable to prove by a preponderance of the evidence.

(5) ORI considered that Respondent blamed others for some of the alleged misconduct. Although Respondent's allegations might not have all been founded, the evidence in this case shows it is more likely than not that others were implicated but they were not investigated or charged.

(6) ORI considered that the laboratory notebook, a copy of which was made during Respondent's interview by Runko and Dahlberg and the original of which was subsequently delivered to Runko by Respondent, had been altered by overwriting or other means. The alterations were made at some unknown time but prior to Respondent's interview with Runko and Dahlberg. ORI Exs. 60, 61. ORI obtained an expert opinion that changes had been made. The changes are obvious to a layperson and the expert is unnecessary. The expert did not opine that Respondent made the changes or when the changes may have been made. ORI Ex. 62. Therefore, attributing the alterations of the laboratory notebook to Respondent is totally speculative and should not be considered an aggravating factor.

(7) ORI also concluded that Respondent was not remorseful. My assessment of Respondent was that he truly believed that he did not commit research misconduct because he believed any errors were the result of honest error and reasonable reliance upon the work of others. Expecting remorse prior to enlightenment is not a reasonable expectation.

III. Conclusion

I recommend the following findings and conclusions:

1. Respondent recklessly caused or permitted 23 instances of research misconduct in his grant applications, articles on which he was the first listed author, and two posters on which he was the first listed author.
2. Appropriate administrative actions are:
 - a. Five-year debarment from any contracting or subcontracting with any agency of the United States and from eligibility for, or involvement in, nonprocurement programs of the United States referred to as "covered transactions." 2 C.F.R. pts. 180 and 376.
 - b. Five-year prohibition from serving in any advisory capacity to PHS, including but not limited to, service on any PHS advisory committee, board, or peer review committee, or as a consultant.
 - c. ORI also proposed that the publisher of certain articles be notified of the need to retract those articles. Retraction has already occurred.



Keith W. Sickendick
Administrative Law Judge