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.

Rakesh Srivastava, Ph.D.,
Respondent.

Docket No. C-15-3830

Decision No. CR5178

Date: September 5, 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).

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[1] Citations are to the 2014 revision of the Code of Federal Regulations (C.F.R.), unless otherwise stated. The 2014 revision is cited as that revision was in effect on July 6, 2015, when the Office of Research Integrity (ORI) notified Respondent of the charge of research misconduct.

The following findings and conclusions are recommended based upon my findings of undisputed fact, my conclusions of law, and my analysis.

1. Respondent, Rakesh Srivastava, Ph.D., intentionally committed research misconduct on June 5, 2012, by submitting to the National Institutes of Health (NIH) grant application R01 CA175776-01 for which he was the principal investigator (PI), and the grant application included plagiarized words.

2. Appropriate administrative actions are:

a. Debarment for two years from any contracting or subcontracting with any federal agency and from eligibility for, or involvement with, nonprocurement programs of the federal government referred to as covered transactions under 2 C.F.R. pts 180 and 276; and

b. Prohibition from serving in any advisory 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 for two years.

I. Procedural History

ORI notified Respondent by letter dated July 6, 2015, of one charge of scientific misconduct, specifically that Respondent:

> [I]ntentionally and knowingly plagiarized scientifically significant text from the Specific Aims and Experimental Methods sections from a grant application under review at the National Institutes of Health (NIH) into [his] grant application, R01 CA175776-01, submitted to NIH eight months later. The plagiarized grant investigated the role of mitochondrial metabolites in cancer, the mechanisms of SIRT4 repression of glutamine metabolism in the regulation of pancreatic cancers, and the role of SIRT4 in DNA damage response in pancreatic cancer. Significant text was included in Respondent's grant application, "Regulation of Mitochondrial Metabolism by SIRT4," with plagiarized text accounting for 40% of the Specific Aims and 50% of the Experimental Methods sections.

ORI Exhibit (Ex.) 29 at 1-2 (Charge Letter). ORI included with its Charge Letter a document titled "The Office of Research Integrity's Findings of Research Misconduct Against Rakesh Srivastava" (ORI Findings). ORI summarized the charge as follows in the ORI Findings:

> [R]espondent intentionally and knowingly submitted extensive plagiarized text in his grant application to obtain PHS funds. Specifically . . . Respondent plagiarized text from grant application 1 R01 CA168662-01 submitted by Principal Investigator Dr. Marcia Haigis of Harvard University to NIH on September 30, 2011, into his grant application 1 R01 CA175776-01 submitted to NIH on June 5, 2012.

ORI Ex. 30 at 2. The section of the ORI Findings titled "ORI Finding" also includes a characterization of the charge similar to that in the Charge Letter. ORI Ex. 30 at 14.

ORI advised Respondent in the Charge Letter that it recommended specific administrative remedies. The administrative remedies listed include debarment for three years from contracting or subcontracting with any federal agency and from eligibility for or involvement with nonprocurement programs of the federal government and prohibition from serving in any advisory capacity to the PHS, including, but not limited to, service on any PHS advisory committee, board, or peer review committee, or as a consultant for three years. ORI Ex. 29 at 2-3.

Respondent's July 29, 2015 request for hearing by an ALJ was received at the Civil Remedies Division (CRD) of the Departmental Appeals Board (DAB) on July 30, 2015. Respondent filed another document by mail on August 21, 2015 with exhibits A through H. The case was assigned to me for hearing and decision on August 28, 2015. On that date, I issued a Notice of Case Assignment and Appointment of Administrative Law Judge (ALJ); Notice of Prehearing Conference; and Prehearing Case Development Order (Prehearing Order), setting an initial prehearing conference for September 21, 2015. Prehearing Order ¶ II.

On September 15, 2015, ORI filed a motion to dismiss Respondent's request for hearing with ORI Exs. 1 through 9. On September 21, 2015, I convened a prehearing conference by telephone, the substance of which is memorialized in my Prehearing Conference Order dated September 23, 2015, and an audio recording of the conference was made available to the parties as DAB E-File Item #12. Respondent indicated during the

conference that he would respond to the ORI motion to dismiss and that he waived oral hearing and further record development.

Respondent filed a response in opposition to the ORI motion to dismiss on September 25, 2015. Respondent's counsel also withdrew from representation on September 25, 2015. The parties advised me in a joint settlement status report on September 29, 2015, that there was a reasonable possibility that this case would settle. On September 29, 2015, I granted ORI 30 additional days to address the grounds for dismissal and the merits of Respondent's case. New counsel entered an appearance on Respondent's behalf on October 7, 2015. ORI filed a reply to Respondent's opposition to the motion to dismiss and the ORI brief on the merits on October 27, 2015, with the declaration of Ann A. Hohmann, Ph.D., which was not marked as an exhibit, and thirty exhibits marked "ORI Hohmann Ex." 1 through 30. On November 13, 2015, ORI advised me in a status report that this case was not likely to settle.

On November 18, 2015, I ordered Respondent to file any objections to the ORI exhibits and any supplemental argument he wished to make. I advised Respondent that if he withdrew the waiver of oral hearing and further record development, I would proceed to decide the ORI motion to dismiss and whether the request for hearing should be granted under 42 C.F.R. § 93.503, before ordering further record development. I granted ORI until January 8, 2016, to respond to any of Respondent's evidentiary objections. On December 15, 2015, I granted Respondent's December 10, 2015 request to withdraw his waiver of oral hearing and further record development. Respondent filed his supplemental argument and evidentiary objections on December 17, 2015. ORI responded to the evidentiary objections on January 6, 2016.

On January 27, 2016, I denied the ORI motion to dismiss Respondent's request for hearing, concluding Respondent timely requested a hearing. I also found that Respondent's request for hearing preserved the following issues for my review: (1) whether the plagiarism alleged in the charge was committed knowingly and intentionally by Respondent; and (2) whether the plagiarism was a significant departure from accepted practices of the relevant research community that Respondent alleges is the University of Kansas Medical Center (KUMC) research community. I found that the following issues were not preserved by Respondent's request for hearing: (1) whether the text in Respondent's grant application R01 CA175776-01 was plagiarized as alleged by ORI; (2) whether the proposed administrative actions are reasonable if research misconduct is proved; and (3) whether Respondent had other defenses not specifically stated in his request for hearing. I concluded that I was required to grant the request for hearing because, based on the record at that time, I determined that there were genuine disputes over facts material to the elements of the charge of research misconduct within

the meaning of 42 C.F.R. § 93.503(a). I made no findings or conclusions as to whether there were genuine disputes of material fact for purposes of summary judgment (*see, e.g.*, Fed. R. Civ. P. 56), as no motion for summary judgment was then pending.

On April 29, 2016, I established a deadline for filing motions for summary judgment as requested by ORI.

On May 24, 2016, ORI filed its exhibit and witness lists with documents marked ORI Ex. 1 through 41. ORI also filed a supplemental declaration of Ann A. Hohmann, Ph.D. and declarations of Patricia Valdez, Ph.D., Michael W. Wolfe, Ph.D., and John Godfrey, none of which were marked as ORI exhibits. On June 30, 2016, ORI filed an amendment to its exhibit list with ORI Exs. 42 through 46, which are the properly marked declaration of Hohmann (ORI Ex. 42) and her supplemental declaration (ORI Ex. 43), and the declarations of Valdez (ORI Ex. 44), Wolfe (ORI Ex. 45), and Godfrey (ORI Ex. 46). Upon comparison, I find that ORI Exs. 1 through 46 include documents previously offered as evidence by ORI but marked differently. For purposes of this decision, I consider only ORI Exs. 1 through 46.

On May 26, 2016, Respondent filed his witness and exhibit lists with exhibits marked Respondent's Exhibits (R. Exs.) 100 through 138. ORI filed objections on June 24, 2016 to R. Exs. 100 and 120 on grounds they are not relevant and material. I agree neither is relevant. R. Exs. 100 and 120 are not admitted or considered as evidence for that reason.

The parties filed joint stipulations of fact (Jt. Stip.), a joint statement of the issues presented, and a joint status report on July 11, 2016.

ORI filed its prehearing brief with four appendices on July 11, 2016. Respondent filed his prehearing brief on July 22, 2016.

Respondent filed R. Exs. 139 and 140 on August 15, 2016. ORI filed ORI Ex. 47 on August 25, 2016.

On September 1, 2016, ORI filed its Memorandum of Points and Authorities in Support of the Government's Motion for Summary Judgment (ORI Br.), with four appendices and other supporting documents. Respondent filed Respondent's Suggestions in Opposition to Government's Motion for Summary Judgment (R. Br.) on October 3, 2016, with supporting documents.

Respondent filed an objection to my consideration of ORI Ex. 47 on September 27, 2016, on grounds the exhibit is offered without adequate foundation. I agree that there is an

inadequate evidentiary foundation for me to determine the relevance and weigh ORI Ex. 47 and the information contained therein. Therefore, ORI Ex. 47 is not admitted and considered as evidence.

ORI Exs. 1 through 46, R. Exs. 101 through 119 and R. Exs. 121 through 140 are admitted and considered as evidence. The appendices filed with the various briefs were not offered as evidence and are not considered as such.

II. Discussion

A. Issues

Whether ORI has shown by a preponderance of the evidence that Respondent committed research misconduct by intentionally and knowingly engaging in "plagiarism in proposing research" and whether 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 (DAB E-File Item #34).

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

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 PHS[2] 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

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[2] There is no dispute that the grant application in issue was submitted to NIH, an agency of PHS. ORI Ex. 1.

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 do the following: 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 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 for Preventing and Reporting Research Misconduct

The Secretary's regulations regarding research misconduct are currently found in 42 C.F.R. pt. 93, which is entitled "Public Health Service Policies on Research Misconduct."[3] 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 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,

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[3] 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).

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, students, 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; 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 a 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. 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 a 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 [sic] intentionally, knowingly, or reckless 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.[4] Ruling on Office of Research Integrity Motion to Dismiss and Order for Further Case Development, dated January 27, 2016 at 8 (DAB E-File Item #22). I have considered the parties' positions in arriving at definitions which I conclude are most likely consistent with the intent of the drafters of the regulations and are most harmonious with the entire regulatory scheme.

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

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[4] 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.

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.[5] 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 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*,[6] intention means "a determination to act in a certain way." Knowing means "having or reflecting knowledge, information, or intelligence." Merriam-Webster.com (last updated August 4, 2018). Reckless means "marked by lack of proper caution" or "careless of consequences." Merriam-Webster.com (last updated August 2, 2018). According to *Black's Law Dictionary*, intentional means "[d]one with the aim of carrying out the act." *Black's Law Dictionary* 826 (8th ed. 2004). 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.* at 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.* at 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 Dictionary*, a layperson'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

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[5] 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).

[6] Merriam-Webster.com (last updated August 4, 2018).

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 propose, perform, review research, or report research results that included false, fabricated, or plagiarized materials, whether or not he 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.

(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. In addition, ORI needs to show that Respondent's conduct is a significant departure from accepted practices within that community.

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.[7] For example, relevant communities could be the

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[7] It is also inexplicable that the drafters of the ORI regulations did not establish a more clear definition of the relevant 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.

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 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 there are other 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. These issues of fact are not material in this case and need not be resolved because the charge of research misconduct involves the accepted practices of the PHS research community, and those accepted practices are established as law by 42 C.F.R. pt. 93.

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. There is no dispute in this case that the allegation of research misconduct is not time barred. ORI received an allegation of possible plagiarism on October 5, 2012, and that allegation was forwarded to KUMC for inquiry on October 19, 2012. ORI Exs. 3; 30 at 3, 4. The research misconduct allegedly occurred on June 5, 2012, when Respondent submitted grant application R01 CA175776-01, for which he was the PI. Jt. Stip.; ORI Ex. 1.

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 comply 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; and 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 DAB. 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, to discovery, to participate in hearings, to present and cross-examine witnesses, and to 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 may not review 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

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

2. Summary judgment is appropriate.

The ORI Charge alleges research misconduct related to a grant application for PHS funding for research. Jt. Stip. ¶ 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 allegation of research misconduct and proposed administrative actions, including debarment or suspension. 42 C.F.R. § 93.500(b).

Pursuant to 42 C.F.R. § 93.506(b)(15), I may resolve a case, in whole or part, upon motion of a party for summary judgment when there is no disputed issue of material fact. Prehearing Order, para. III.B.3.a. advised the parties that they could file a motion for full or partial summary judgment. I advised the parties:

> A party opposing a motion or cross-motion for summary judgment on grounds that there is a material issue of fact in dispute must submit evidence, documents or affidavits/declarations, to show that a disputed issue of fact exists.
>
> * * * *
>
> [A] fact alleged and not specifically denied, may be accepted as true for purposes of a motion or cross-motion for summary judgment. Any evidence will be considered admissible and true, unless specific objection is made to its admissibility and accuracy.

On April 28, 2016, ORI requested that I amend the schedule for prehearing development of this case to permit the filing of motions for summary judgment. ORI stated in the motion that Respondent did not object to the motion. Motion to Amend January 27, 2016 Case Development Order at 1 (DAB E-File Item #24). On April 29, 2016, I issued an order establishing a deadline for filing motions for summary judgment. DAB E-File Item #25.

The Civil Remedies Division Procedures (CRDP) § 19(a) (DAB E-File Item #5b), which were provided to the parties with the Prehearing Order, advised the parties that a motion for summary judgment would be subject to Fed. R. Civ. P. 56 and related federal case law or ALJ order. In this case, the parties both cite Fed. R. Civ. P. 56 and related cases. ORI Br. at 3-4; R. Br. at 2. Therefore, the parties were clearly on notice of the legal authorities to be applied in deciding a motion for summary judgment.

Summary judgment is granted when "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Matsushita Elec. Indus. Co. v. Zenith Radio*, 475 U.S. 574, 587 (1986). A party, movant or nonmovant, must support an asserted factual position by citing to materials of record that support its position. Fed. R. Civ. P. 56(c). When confronted with a properly supported motion for summary judgment, the

nonmoving party "may not rest upon the mere allegations or denials of his pleading, but . . . must set forth specific facts showing that there is a genuine issue for trial." *Anderson*, 477 U.S. at 248 (quoting *First Nat'l Bank of Az. v. Cities Serv. Co.*, 391 U.S. 253, 249 (1968)); Fed. R. Civ. P. 56(c). In opposing a motion for summary judgment, the nonmovant bears the burden of showing that there are material facts that are disputed, either affecting the movant's prima facie case or that might establish a defense. It is insufficient for the nonmovant to rely upon mere allegations or denials to defeat the motion and proceed to hearing. The nonmovant must, by affidavits or other evidence, present facts that show there is a genuine issue for trial. If the nonmovant cannot show by some credible evidence that there exists some genuine issue for trial, then summary judgment is appropriate and the movant prevails as a matter of law. *Anderson*, 477 U.S. 242, 247. A test for whether an issue is regarded as genuine is if "the evidence [as to that issue] is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* at 248. In evaluating whether there is a genuine issue as to a material fact, an ALJ must view the facts and the inferences to be drawn from the facts in the light most favorable to the nonmoving party. *Matsushita*, 475 U.S. at 587. On summary judgment, the judge does not make credibility determinations and weigh the evidence but draws all justifiable inferences in favor of the nonmovant. *Anderson*, 477 U.S. at 255.

I conclude that there is no genuine dispute as to material facts and ORI prevails as a matter of law on the issues presented for decision in this case, including the appropriateness of the proposed administrative actions.

3. Respondent engaged in research misconduct intentionally.

a. Facts

On July 11, 2016, the parties filed their joint stipulations of fact. They stipulated that Respondent was employed at the University of Kansas Medical Center Department of Pharmacology, Toxicology and Therapeutics from 2009 until July 2014. Respondent had been a regular reviewer for NIH since 2004. Marcia Haigis, Ph.D., Harvard University, submitted grant application R01CA168662-01 to NIH on September 30, 2011 (the Haigis grant application). Respondent submitted his grant application, R01CA175776-01, to NIH on June 5, 2012 (Respondent's grant application). Respondent was the PI for his grant application. Text from the Haigis grant application was contained in Respondent's application without attribution to Haigis. Jt. Stip. Respondent admitted many of the same facts in "Respondent's Response to Government's Statement of Material Facts Not in Dispute" filed on October 3, 2016 (DAB E-File Item #44).

b. Analysis

The four elements that ORI must prove in this case by a preponderance of the evidence to establish that Respondent committed research misconduct are: (1) there was plagiarized material; (2) the plagiarized material must have been used in a grant application to NIH; (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 or knowingly. 42 C.F.R. § 93.04. Plagiarism is the "appropriation of another person's ideas, processes, results, or words without giving appropriate credit." 42 C.F.R. § 93.103(c). The regulations do not establish how many words are required for plagiarism to occur or how significant the words or concepts conveyed by those words must be. The first element is satisfied by Respondent's admission that words from the Haigis grant application were in Respondent's grant application without giving credit for those words to Haigis. Jt. Stip.; ORI Ex. 28 at 2; R. Br. at 4. The second element is satisfied, as there is no dispute that the words from the Haigis grant application were in Respondent's grant application to the NIH. In this case, Respondent's grant application was not approved and was unfunded. I conclude that Respondent's grant application is nevertheless a basis for a charge of research misconduct. The applicable regulations clearly apply to applications or proposals for PHS support. 42 C.F.R. §§ 93.102(b)(1)(i), .103. The prohibition against research misconduct is not limited to funded grant applications. The third element is also satisfied in this case. As previously explained, 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. Plagiarism in a grant application to NIH for PHS funded support is research misconduct. Even if Respondent could present evidence that plagiarism may be acceptable or even common in another research community, such as one identified or defined, for example, by an institution, a type of research, or by geography, that fact would have no effect on the outcome in this case because plagiarism is clearly research misconduct as a matter of law in the relevant community of researchers and institutions that apply for PHS funding. The fourth element is the element that is truly at issue in this case.

The fourth element necessary to establish research misconduct is mental state or scienter. ORI charged that Respondent "intentionally and knowingly" used plagiarized text in his grant application. ORI Ex. 29 at 1; ORI Ex. 30 at 2. It is not clear why ORI did not charge Respondent with committing research misconduct intentionally, knowingly, or recklessly as any of these scienter requirements alone would be sufficient. However, it is not my province to examine the ORI investigation or the charging decision. ORI notified Respondent that the charge was that he "intentionally and knowingly" committed research misconduct and that is the charge Respondent was required to address.

However, under 42 C.F.R. § 93.104(b), it is sufficient for me to find that Respondent either intentionally or knowingly engaged in conduct in order for the fourth element necessary to establish research misconduct to be satisfied. Because ORI did not charge Respondent with acting recklessly, I have ruled that I would not consider that mental state in this case. Ruling on Office of Research Integrity Motion to Dismiss and Order for Further Case Development at 7. In the foregoing discussion of the regulatory scheme, I discussed my conclusion and rationale that 42 C.F.R. § 93.104(b) requires that ORI must prove by a preponderance of the evidence, that Respondent:

- Intended to propose, perform, or review research, or report research results that included false, fabricated, or plagiarized materials, whether or not he accomplished the use of such materials; or

- Used false, fabricated, or plagiarized materials knowing that they were false, fabricated, or plagiarized.

Respondent argues that summary judgment is not appropriate in this case, as there is a genuine dispute of material fact as to Respondent's knowledge and intent when he submitted his grant application. R. Br. at 4-5. Respondent cites his declaration in which he denies placing the plagiarized words in his grant application and denies knowledge of how those words came to be in his grant application. R. Ex. 103 at 1-2 ¶¶ 6, 9-11; ORI Ex. 28 at 1-2 ¶¶ 6, 9-11. Respondent has been somewhat inconsistent about whether he did all the drafting of his grant or whether others were involved in drafting. Respondent told the inquiry committee that he was solely responsible for the plagiarized text of his grant application. R. Ex. 136 at 1-2 ¶ 3; R. Ex. 137 at 1-2 ¶ 3; R. Ex. 138 at 1-2 ¶ 3; ORI Ex. 7 at 1, 3, 5; ORI Ex. 8 at 2. However, during the KUMC investigation he told the investigators that he had postdoctoral fellows or others assist him with the grant. R. Ex. 102 at 18-19, 22, 41-42, 45; ORI Ex. 9 at 18-19, 21-22. In his responses to the KUMC investigation report, Respondent stated he acknowledged his grant proposal was "largely authored by him, but that others participated." ORI Ex. 14 at 1; ORI Ex. 15 at 13. For purposes of summary judgment, I accept as true Respondent's assertion that others assisted him with drafting the grant application. I also accept as true that he did not put the plagiarized words in his grant application and that he has no knowledge how the plagiarized words came to be in his grant application. Respondent does not dispute that there were plagiarized words in his grant application or that the plagiarized words were in the grant application when he submitted it to NIH.

Respondent comments that I might be able to infer from the undisputed facts the intent to use plagiarized materials or the knowing use of plagiarized materials, but he argues that drawing such an inference against Respondent is not appropriate on summary judgment,

citing *Anderson*, 477 U.S. at 355. R. Br. at 4-5. I agree with Respondent's interpretation of *Anderson*, but it is not necessary for me to draw any inference adverse to Respondent. Respondent's view is that ORI must prove that Respondent knew or intended that there be plagiarized words in his grant application. However, that is not the case based on my interpretation of the regulations. ORI need only show that Respondent, as the PI, intended to submit his grant application and that grant application included plagiarized words. I find nothing in the regulations or their history that suggests that ORI is required to prove it was more likely than not that Respondent inserted the plagiarized words or that he had the specific intent to use plagiarized words.[8] Thus, even though I may accept as true for purposes of summary judgment Respondent's assertions that he did not know or that he did not intend for there to be plagiarized words in his grant application, there is no dispute that plagiarized words were in the grant application (R. Br. at 4) and Respondent intended to and did submit the application. I conclude that is all that is required to satisfy the fourth element required to prove research misconduct.

The plain language of the regulations supports my construction and application. 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 who is 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. The issue to be resolved is whether Respondent may be held liable for research misconduct in a PHS grant proposal in which there is plagiarized material, even if the evidence does not show it is more likely than not that he intentionally and knowingly used the plagiarized material in his grant proposal. The answer is clearly yes. So long as the required act of proposing PHS supported research occurred and plagiarized materials were used, under the broadly

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[8] The regulations do not require that ORI prove specific intent. 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).

drafted 42 C.F.R. pt. 93, one listed as having responsibility for the action, such as a PI, may be found liable for the research misconduct, even though I accept as true for purposes of summary judgment Respondent's representation that he committed no act other than submitting the grant proposal that included plagiarized words. 42 C.F.R. § 93.103. Accordingly, Respondent's defensive argument that he did not know or intend to include plagiarized words in his grant application must be resolved against him as a matter of law.

Respondent does not assert honest error or difference of opinion as defenses to the ORI charge. Therefore, I conclude that consideration of how such assertions might affect his intent do not present a triable issue in this case.

4. Administrative actions proposed by ORI are not reasonable based on this recommended decision on summary judgment.

Summary judgment is also appropriate on the issue of whether the ORI proposed administrative actions are reasonable. How I am to determine the appropriateness of proposed 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 three years from contracting or subcontracting with any federal agency and from eligibility for or

involvement with nonprocurement programs of the federal government and prohibition from serving in any advisory capacity to the PHS, including, but not limited to, service on any PHS advisory committee, board, or peer review committee, or as a consultant for three years. ORI Ex. 29 at 2-3; ORI Ex. 30 at 17-18.

ORI's evaluation of the aggravating and mitigating circumstances in Respondent's case is set forth in ORI Ex. 30 at 16-17. Several of the aggravating factors cited by ORI would require an oral hearing to determine whether those factors are supported by a preponderance of the evidence. 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). Therefore, I consider only those factors for which there is clearly no genuine dispute of material fact. If ORI wishes to attempt to prove the additional aggravating factors it cites, ORI may file a motion to reopen and proceed to a trial.

I consider the following factors from 42 C.F.R. § 93.408 for which there is no genuine dispute of material fact:

> (a) Respondent intentionally submitted his grant application that included plagiarized words to NIH (42 C.F.R. § 93.408(a));
>
> (b) There was no pattern of research misconduct as the current record reflects that Respondent's conduct was an isolated event (42 C.F.R. § 93.408(b));
>
> (c) Respondent's grant was not funded and there is no undisputed evidence of any significant impact on the proposed research record, research subjects, other researchers, institutions, or the public health and welfare (42 C.F.R. § 93.408(c));
>
> (d) Respondent admitted that his grant application contained plagiarized words but denied that he placed them in the grant application (42 C.F.R. § 93.408(d));
>
> (e) Respondent did attempt to shift blame to his research assistants or postdoctoral fellows for adding the plagiarized words to his grant application, but I recognize that is part of his defense to the charge of research misconduct and he has the due process right to defend himself (42 C.F.R. § 93.408(e));
>
> (f) There is no evidence of any retaliation by Respondent (42 C.F.R. § 93.408(f));

(g) It is not known whether Respondent is presently sufficiently responsible to conduct PHS supported research (42 C.F.R. § 93.408(g)); and

(h) There are no other factors considered (42 C.F.R. § 93.408(h)).

My findings of aggravating and mitigating factors are based on the undisputed facts as this decision is based on a favorable ruling on the ORI motion for summary judgment. ORI recommended a three-year debarment on contracting and a three-year prohibition on serving in an advisory capacity to PHS based on aggravating factors, some of which could only be determined after a trial on the merits. Because this matter is resolved on summary judgment at ORI's behest and I find fewer aggravating factors than ORI, I conclude that ORI's proposed administrative actions are unreasonable. I conclude after de novo review that a two-year bar and two-year prohibition are reasonable.

III. Conclusion

I recommend the following findings and conclusions:

1. Respondent intentionally committed one instance of research misconduct by submitting to NIH a grant application that included plagiarized words.

2. Appropriate administrative actions are:

   a. Debarment for two years from any contracting or subcontracting with any federal agency and from eligibility for, or involvement with, nonprocurement programs of the federal government referred to as covered transactions under 2 C.F.R. pts 180 and 276; and

   b. Prohibition from serving in any advisory capacity to the PHS, including, but not limited to, service on any PHS advisory committee, board, or peer review committee, or as a consultant for two years.

Keith W. Sickendick
Administrative Law Judge