UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

RAKESH KUMAR, Ph.D., **Plaintiff,** v. **GEORGE WASHINGTON UNIVERSITY,** **Defendant.**	**Civ. No. 1:15-cv-00120-JDB**

PLAINTIFF'S OPPOSITION TO DEFENDANT'S MOTION TO DISMISS FIRST AMENDED COMPLAINT FOR LACK OF SUBJECT MATTER JURISDICTION

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Plaintiff, Dr. Rakesh Kumar ("Dr. Kumar" or "Plaintiff"), by and through his undersigned counsel, hereby opposes Defendant George Washington University's ("GW" or "Defendant") Motion to Dismiss the First Amended Complaint for Lack of Subject Matter Jurisdiction and states as follows:

INTRODUCTION

With scant legal analysis, GW seeks to be treated as a federal government agency absolutely immune from all of Dr. Kumar's claims. GW contends that its actions which are the subject of this litigation constitute discretionary delegated government functions for which GW is immune. On that basis, GW seeks dismissal of Dr. Kumar's First Amended Complaint ("FAC") under Rule 12(b)(1) of the Federal Rules of Civil Procedure based on a lack of subject matter jurisdiction. To prevail on its Motion, GW bears the burden of demonstrating that the conduct was both delegated and discretionary. This it has not done.[1] GW's arguments need not even be considered, however, because there is a threshold barrier to its immunity claim – lack of legislative action conferring immunity. Because GW has failed to demonstrate that it is immune from liability for the claims asserted in the First Amended Complaint, GW's motion should be denied.

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[1] GW's legal arguments fall woefully short of meeting GW's burden. GW's four page supporting Memorandum makes assumptions and distortions of the regulatory record that are not analytically grounded in fact or law. To respond with actual analysis of the immunity issue, rather than mere counter-assumptions, and to provide the Court with the necessary regulatory background, requires more than four pages.

ARGUMENT

I. THE GOVERNMENT HAS DECLINED TO AFFORD INSTITUTIONS IMMUNITY IN THESE CIRCUMSTANCES

GW seeks to have this case dismissed by asserting the protection of the absolute immunity to tort claims[2] which is usually reserved for the government. The burden to prove immunity lies with GW. *Weissman v. NASD*, 500 F.3d 1293, 1296 (11th Cir. 2007) (burden of proof is on party asserting immunity). The Supreme Court "has generally been quite sparing in its recognition of claims to absolute official immunity." *Forrester v. White*, 484 US 219, 224 (1988). Here, the Court need not even consider the arguments on which GW seeks immunity because the government has already addressed the issue and has failed to take the steps necessary to shield any institution, to include private institutions such as GW, from claims brought by respondents in scientific misconduct cases. Whether an investigating committee should be immune from claims arising from research misconduct investigations was considered by the Office of Science and Technology Policy ("OSTP")[3] in the very same policy statement cited by GW at page 3 of its Memorandum of Points and Authorities in Support of Its Motion to Dismiss the First Amended Complaint for Lack of Subject Matter Jurisdiction ("Memo." or "Memorandum"). In its Notice of Final Policy setting for the Federal Research Misconduct Policy, OSTP addressed in a question/answer format a number of comments which OSTP had received in response to the Request for Public Comment, including the following question/answer:

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[2] As discussed below, GW's arguments do not even apply to Dr. Kumar's breach of contract claim.

[3] OSTP was established pursuant to the Presidential Science and Technology Advisory Organization Act of 1976. 42 U.S.C. §6611 (P. Law 94-282 at §202) (May 11, 1976).

> *Why doesn't the policy provide immunity for research misconduct investigative committees?* Providing immunity to research misconduct investigative committees and other participants in institutional and agency research misconduct proceedings would require significant statutory or regulatory initiatives which will be explored separately from this policy.

65 Fed. Reg. 76261 (Dec. 6, 2000) (italics in original). Clearly, the Court cannot simply imply immunity in favor of GW as GW has invited it to do. GW has not cited to any "significant statutory or regulatory initiative" after the 2000 OSTP Notice of Final Policy which would support the grant of immunity here. In fact, as the foregoing states, not even participants in *agency* research misconduct proceedings have immunity.

The issue of immunity arose again less than five years later, this time within the Department of Health and Human Services ("HHS"). In issuing its Final Rule for Public Health Service Policies on Research Misconduct, HHS responded to comments in a question/answer format just as the OSTP had in 2000. The following question/answer appears:

> Q. Should HHS take action to provide immunity from personal liability for institutions, committee members, and witnesses who participate in research misconduct proceedings?
>
> A. As the commentator who raised this issue implied, ***a Federal statute, rather than an HHS regulation, would be needed to provide this immunity. Earlier attempts by HHS to develop legislation providing immunity were unsuccessful.*** ORI does not currently have sufficient data to make the case for Federal legislation. Interested parties are encouraged to submit evidence that would help us in determining whether there is a need for Federal legislation to provide immunity for committee members and witnesses or to propose ways to provide such protection in the absence of such legislation.

70 Fed. Reg. 28370, 28380 (May 17, 2005) (emphasis added).

Thus, this Court does not write on a clean slate in addressing the question of immunity. Both the OSTP and HHS are keenly aware of the issue and both have stated that, in the absence

of a legislative or regulatory initiative to put such immunity into place, there is no such immunity. Although GW's request for immunity should therefore be denied on this basis alone, Dr. Kumar responds below to GW's arguments regarding delegated discretionary functions.

II. THE ACTIONS AT ISSUE WERE NOT "DELEGATED"

Federal government officials are immunized from liability for state-law tort liability where the conduct is discretionary and within the "outer perimeter" of the employee's duties. *Westfall v. Erwin*, 484 U.S. 292, 300 (1988). If the function is one for which the government itself would usually be entitled to immunity, but the government has delegated the performance of the function to a non-governmental entity, then the entity may also be entitled to immunity. *Mangold v. Analytic Servs. Inc.*, 77 F.3d 1442, 1447-48 (4th Cir. 1996). Essentially, the immunity (if any) passes with the delegation. Because GW, a private institution, would not typically be entitled to such immunity, it must first establish both that a government agency would have been immune had it undertaken the same function and that the agency delegated that function to GW. GW has not, and cannot, meet this test.

A. The Purported Delegating Agencies Are Not Immune

Before reaching the question of whether GW performed a discretionary function, the Court must determine whether GW's investigation was a function for which the government would have been immune and whether the government delegated its function to GW. Dr. Kumar submits that this case does not involve such a "delegated" function and therefore, for this additional reason, GW is not protected by immunity.

GW cannot even get past the first hurdle of demonstrating that had a government agency performed the function itself, the agency would have been immune. Here, as noted above, not even the agencies would be immune from the type of claims brought by Dr. Kumar. *See* 65 Fed.

Reg. 76261 (Dec. 6, 2000) (there is no immunity for "research misconduct investigative committees and other participants in institutional *and agency* research misconduct proceedings") (emphasis added). Because the agencies themselves have no immunity, there can be no derivative immunity for any private institution. *McCue v. City of New York*, 521 F. 3d 169, 196 (2nd Cir. 2008) ("Defendants will have to show that the actions for which they seek derivative immunity were controlled by agencies that were, themselves, entitled to Stafford Act immunity"). Thus, GW's claim to immunity fails because it cannot establish this factor.

B. There was No Actual Delegation of Authority

GW has also failed to establish the second factor, that the investigative function was an obligation of the government which was *delegated* to GW. In a delegated function case such as will afford the delegated entity the protection of immunity (unlike in this case), the delegating entity has duties and obligations under a statute or regulation which it then delegates to another government agency or to a private contractor. The entity receiving the delegation then stands in the shoes of the first entity. For example, in *Pani v. Empire Blue Cross Blue Shield*, 152 F.3d 67 (2nd Cir. 1998), one of the cases cited by GW, the statute expressly provides that "[t]he administration of this part shall be conducted ***through contracts*** with medicare administrative contractors under section 1395kk–1 of this title." 42 U.S.C. §§ 1395h, 1395u (emphasis added). The government entered into a contract with defendant Empire Blue Cross Blue Shield pursuant to which Empire administered ***the government's*** obligations under parts A and B of Title 42. Thus, under the statutory framework, the government contracts out (delegates) its administrative duties to a private medicare administrative contractor. Empire Blue Cross Blue Shield was such a contractor. In affording Empire immunity against the claims, the Court explained that fiscal intermediaries and contractors are "acting as adjuncts to the government and are carrying out a

traditional government function." *Pani*, 152 F.3d at 74. Because the government would be immune if it administered the program, the private contractors who administer the program on behalf of the government are also immune. *Pani*, 152 F.3d at 72. By delegating its own duties to a private entity, the government is able to rely on another entity to accomplish what the government would otherwise have had to do itself. *See Mangold v. Analytic Servs.*, 77 F.3d 1442, 1448 (4th Cir. 1996) (because the "government cannot perform all necessary and proper services itself," it must sometimes delegate some functions through contracting with private contractors).

GW includes a lengthy quotation from *Mangold v. Analytic Servs.*, 77 F.3d 1442, 1449 (4th Cir. 1996) about the application of absolute immunity where a government function has been delegated. GW's Memo. at 3. According to *Mangold*, performance of a discretionary government function is immune no matter how many times the function may have been delegated and re-delegated. *Mangold*, however, involved a private entity which had contracted with the federal government to provide services in connection with federal government acquisitions, especially by the Air Force. 77 F.3d at 1444. The investigation which took place, however, was actually conducted by the government (the Air Force). 77 F.3d at 1445, 1449. There was no delegation of that function. The issue regarding delegation arose in the very narrow context of whether the government contractor witnesses who gave testimony during the Air Force's investigation of abusive practices connected with the contract should be immune from state law tort claims asserting that their testimony injured the reputations of the plaintiffs. The court granted immunity because had the government not delegated the acquisition services to a private contractor, then the government would have provided those services and it would have been a government employee giving the testimony. The grant of immunity was also based

on the common law privilege of witnesses to testify with immunity in court, before grand juries and before government investigators. 77 F.3d at 1449. The court's grant of immunity was very narrow: "Therefore, we apply such immunity only insofar as necessary to shield statements and information, whether truthful or not, given by a government contractor and its employees *in response to queries* by government investigators engaged in an official investigation." 77 F.3d at 1449 (emphasis in original).

McCue v. City of New York, 521 F. 3d 169 (2nd Cir. 2008) was brought by more than sixty plaintiffs who were at Ground Zero during the clean-up after the September 11, 2001 terrorist attack. The plaintiffs included construction workers, firefighters, policemen and others. More than half of the plaintiffs alleged that they suffered respiratory injuries caused by the failure of the various defendants, including the Port Authority of New York and New Jersey (the "Port Authority"), to monitor conditions, provide adequate safety equipment, and warn the plaintiffs of the dangerous conditions present at the site. 521 F.3d at 173. Citing *Pani* (also relied on by GW here), the Port Authority asserted that it was immune from suit by virtue of derivate federal immunity. 521 F.3d at 198. One of the grounds on which the court rejected the Port Authority's argument was that the Port Authority's role, unlike Blue Cross in the *Pani* case, "was not that of an intermediary hired by the federal government to perform a delegated official function." 521 F.3d at 200. Like the Port Authority, although GW cites to *Pani*, it has failed to demonstrate that its role in conducting internal research misconduct investigations is like that of an "intermediary hired by the federal government to perform a delegated official function."

In *Watson v. Philip Morris Companies, Inc.*, 551 U.S. 142 (2007),[4] Philip Morris, a non-governmental entity, argued that the government had delegated to it the responsibility for conducting testing on cigarettes and that it should therefore be treated as a government entity for purposes of the officer removal statute. For twenty years, the FTC used its own laboratories to conduct tar and nicotine tests on cigarettes, using a test developed by an employee from the Department of Agriculture, and periodically published the test results. 551 U.S. at 155. Because the costs to the government for testing grew too high, the FTC stopped conducting the tests itself in 1987. 551 U.S. at 155. The cigarette manufacturers took over testing, using government specifications. 551 U.S. at 155. They are required to disclose information about tar and nicotine based on these tests. 551 U.S. at 156. Philip Morris argued that the shift in 1987 from testing by the government in its own lab to testing by the cigarette manufacturers in industry financed labs constituted a "delegation" of a government function. 551 U.S. at 154, 156. The Court, having "found no evidence of any delegation of legal authority from the FTC to the industry association to undertake testing on the Government agency's behalf," rejected that argument. 551 U.S. at 156. Significantly, the Court then stated that "neither Congress nor federal agencies normally delegate legal authority to private entities without saying that they are doing so." 551 U.S. at 157. Neither HHS nor ORI has done so here and Dr. Kumar respectfully requests the Court to reject GW's argument that its investigation of Dr. Kumar was a "delegated government function."

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[4] *Watson* involved the question of whether a private entity could remove a state action to federal court based on the officer removal statute. Although not an immunity case, *Watson* is instructive because the private entity defendant could remove only if it could establish that it had been delegated a government function such that it should be treated as a governmental entity.

GW has failed to cite to any legal authority establishing that ORI was tasked with the primary responsibility of conducting investigations of research misconduct occurring at private universities but then "delegated" that responsibility to the private universities. This failure is fatal to GW's request for immunity. GW states: "Pursuant to the Public Health and Welfare Act,[5] the Office of Research Integrity (ORI) is responsible for investigating all reports of research misconduct from institutions receiving Public Health Service (PHS) funding." GW's Memo. at 3 (footnote added). The laws and regulations regarding scientific research misconduct do not support GW's argument, however.

Section 483 of the Health Research Extension Act of 1985 ("HREA"), Pub. L. No. 99-158, 99 Stat. 820 (Nov. 20, 1985)[6] requires the Secretary of Health and Human Services to promulgate regulations requiring each entity that applies for a grant for any project that involves biomedical or behavioral research to submit with its grant application assurances that it has established, in accordance with regulations to be prescribed by the Secretary, "an administrative process to review reports of scientific fraud in connection with biomedical and behavioral research conducted at or sponsored by such entity[.]" HREA at §493(a)(1). The entity is required to report to the Secretary any investigation of fraud which appears substantial. *Id.* at §493(a)(2). In a 1993 amendment to the HREA, ORI was created: "Not later than 90 days after June 10, 1993, the Secretary shall establish an office to be known as the Office of Research

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[5] GW does not give a citation to the "Public Health and Welfare Act" on which it purports to rely. In fact, that reference is a misnomer. "Public Health and Welfare" is the name given to Title 42 of the United States Code. Title 42 of course contains many different acts concerning the public health and welfare. Although a few cases make the same improper reference, the United States Code does not appear to contain any such named act.

[6] The HREA was an amendment to the Public Health Service Act, Pub. L. No. 410, 58 Stat. 682 (1944).

Integrity . . . which shall be established as an independent entity in the Department of Health and Human Services." 42 U.S.C. §289b(a)(1). The 1993 amendment revised the 1985 version to provide that institutions would report their investigations of alleged research misconduct to the ORI Director rather than the Department Secretary. 42 U.S.C. §289b(b)(2). Like the 1985 version, the 1993 amendment retained the requirement that each institution applying for federal research funds make satisfactory assurances to the Secretary that it has in place an "administrative process to review reports of research misconduct in connection with biomedical and behavioral research conducted at or sponsored by such entity." 42 U.S.C. §289b(b)(1).[7] Thus, the statutory scheme applicable to HHS has consistently required institutions to adopt policies for reviewing allegations of research misconduct.

Approximately seven years after the 1993 amendment was enacted, the OSTP, as noted at the outset of this Opposition, published the Federal Research Misconduct Policy (the "Federal Policy"). 65 Fed. Reg. 76260 (Dec. 6, 2000). The Federal Policy requires all federal agencies that conduct or support research to implement the Policy. 65 Fed. Reg. 76270. The purpose of the Federal Policy was to develop a uniform policy governing research misconduct that would be implemented by all federal agencies that conduct or support research. 65 Fed. Reg. 76260. It is this Federal Policy that GW quotes in its Memorandum, as follows: "Agencies and research institutions are partners who share responsibility for [the] research process. Federal agencies have ultimate oversight authority for Federally funded research but research institutions bear primary responsibility for prevention and detection of research misconduct and for the inquiry, investigation and adjudication of research misconduct alleged to have occurred in association

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[7] The one change made in this provision was the 1993 amendment's substitution of the phrase "research misconduct" in place of the 1985 provision's phrase "scientific fraud."

with their own institution." GW's Memo. at n.3 (quoting 65 Fed. Reg. 76260, 76263 (Dec. 6, 2000)). This policy statement does not state that ***ORI*** is responsible for investigating all reports of research misconduct, yet that is the proposition for which GW cited it.[8] The policy expressly states, as does the HREA and the 1993 amendment to the HREA, that the ***institutions*** are primarily responsible for investigating research misconduct occurring at their institutions. 65 Fed. Reg. 76260, 76263. The Federal Policy defines "'research institutions' as including *all* organizations using Federal funds for research, including, for example, colleges and universities, *intramural Federal research laboratories*, Federally funded research and development centers, national user facilities, industrial laboratories, or other research institutes. Independent researchers and small research institutions are covered by this policy." 65 FR 76260, 76262 n.4 (emphasis added). Thus, intramural Federal research laboratories are included within the definition of "research institution" and have primary responsibility for investigating allegations of misconduct occurring at their laboratories. As discussed earlier, one of the reasons functions are delegated to private entities is to relieve the government of the burden of having to perform the function itself (as in the administration of medicare); the fact that Federal laboratories are responsible for conducting their own misconduct investigations would not achieve this goal. The reason institutions (whether private or government) conduct their own investigations is not to relieve the government of some overwhelming burden; it is because institutions are closer to the conduct that is the subject of the allegations. 65 Fed. Reg. 76260, 76262.

GW has cited to no authority which actually supports its contention that ORI is responsible for investigating all reports of research misconduct. GW cites 42 C.F.R. Section

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[8] In fact, the Federal Policy does not even mention ORI, as the Policy is a general policy applicable to ***all*** federal agencies involved in funded research.

93.100 to support its contention that ORI has "delegated" to institutions receiving Public Health Services Funding (such as GW) the primary responsibility for investigating allegations of scientific research misconduct. GW's Memo. at 3. Again, however, GW's citation does not support its argument that there was a delegation of ORI's authority. Section 93.100 states that HHS and institutions "share responsibility" for the integrity of the research process. Section 93.100 then explains how that responsibility is shared. HHS is responsible for "ultimate oversight authority for PHS supported research" and institutions "have an affirmative duty to protect PHS funds from misuse . . . and ***primary responsibility*** for responding to and reporting allegations of research misconduct, as provided in this part." 42 C.F.R. §93.100 (emphasis added). This simply is not a case of a delegated government function.

In its request for public comment on the then proposed federal policy on research misconduct, the OSTP stated:

> It is expected that the final policy will apply to all research funded by the Federal agencies, including intramural research conducted by the Federal agencies, research conducted or managed by contractors, and research performed at universities. Commentators are invited to express their views on the proposed policy and on the premise that a uniform government-wide policy is a desirable goal.

64 Fed. Reg. 55723 (Oct. 14, 1999). As this statement explains, there are different types of institutions in which federally funded research is undertaken and, thus, different types of institutions in which research misconduct can occur. Allegations of misconduct in federally funded research occurring at a private educational institution such as GW is but one example. Allegations of misconduct can also arise from intramural research carried out by a federal agency (such as the National Institutes of Health or the National Science Foundation) or from research conducted or managed by contractors. When the research misconduct allegations concern research conducted at a federal research laboratory, that federal laboratory has primary

responsibility for conducting the investigation. When the research misconduct allegations concern research conducted at a university, that university has primary responsibility for conducting the investigation.

HHS's implementation of the Federal Policy is found in Part 93 of Title 42 of the Code of Federal Regulations. The purpose of Part 93 is to "[e]stablish the responsibilities of HHS, PHS, the Office of Research Integrity (ORI), and the institutions in responding to research misconduct issues[.]" 42 C.F.R. 93.101(a). Thus, under HHS's regulatory scheme, the institutions involved in research have responsibilities separate from ORI. None of the regulations state that ORI has "delegated" its investigatory responsibilities to the Institutions. By contrast, the regulations do specifically refer to HHS's delegation of authority to ORI. "Office of Research Integrity" and "ORI" are defined as "the office to which the HHS Secretary has *delegated* responsibility for addressing research integrity and misconduct issues related to PHS supported activities." 42 C.F.R. §93.217 (emphasis added). "Secretary or HHS. Secretary or HHS means the Secretary of HHS or any other officer or employee of the HHS to whom the Secretary *delegates* authority." 42 C.F.R. § 93.227 (emphasis added). "The ALJ is bound by all Federal statutes and regulations, Secretarial *delegations* of authority, and applicable HHS policies and may not refuse to follow them or find them invalid, as provided in paragraph (c)(4) of this section." 42 C.F.R. § 93.506 (emphasis added). The fact that there are express delegations of authority in the regulations, but no express delegation by ORI of its authority to institutions, further weakens GW's argument that ORI was primarily responsible for conducting all investigations and then delegated that investigatory authority to GW.

As discussed above, in a case where there is actual delegation (for example, in *Pani*), the government is relieved of a particular administrative burden because it passes its responsibility to

a private entity. That particular benefit is not present under the Federal Policy or HHS's policy because ORI itself may conduct its own investigation concurrently with a university's (or any other institution's) investigation. Under 42 C.F.R. Section 93.400(a), ORI "may respond directly to any allegation of research misconduct at any time before, during, or after an institution's response to the matter." This is further evidence that ORI has not "delegated" responsibility for investigations to the institutions.

All of these provisions demonstrate that institutional investigations are a primary responsibility of the institutions rather than a delegated function of ORI. The case law and regulatory provisions support Dr. Kumar's argument that ORI has not delegated any function to GW and that GW is simply regulated by federal law as a condition of its receipt of federal research funds.

C. Institutions Can Determine Their Own Policies

That GW's investigatory activity is not a delegated function is further shown by the fact that the applicable federal regulations permit institutions such as GW to adopt their own policies and procedures pertaining to research misconduct matters. The Federal Policy includes guidelines for institutions and agencies in "developing fair and timely procedures for responding to allegations of research misconduct." 65 Fed. Reg. 76260, 76263. However, the Federal Policy "does not limit the authority of research institutions, or other entities, to promulgate additional research misconduct policies or guidelines or more specific ethical guidance." 65 Fed. Reg. 76260, 76264. Consistent with that statement, the HHS regulations provide that "[i]nstitutions may have internal standards of conduct different from the HHS standards for research misconduct under this part. Therefore, an institution may find conduct to be actionable under its standards even if the action does not meet this part's definition of research

misconduct." 42 C.F.R. Section 93.319(a). In fact, a finding by, or settlement with, HHS "does not affect institutional findings or administrative actions based on an institution's internal standards of conduct." 42 C.F.R. § 93.319(b). The OSTP also provides that "[t]he Federal agency will make the final decision about whether to make an agency finding of research misconduct. However, within its own internal jurisdiction, a non-Federal research institution may establish policies and take actions as appropriate to its needs and as consistent with other relevant laws." 65 FR 76260, 76262.

Not only did GW adopt its own policy as permitted by both the Federal Policy and HHS's regulations, it completely ignores the fact that Dr. Kumar's claims are based on ***GW's*** research misconduct policy (not the Federal Policy or HHS's regulations), a policy that is part of Dr. Kumar's contract with GW.[9] GW's research policy says nothing about GW being an entity delegated by the government to conduct research misconduct investigations on behalf of the government nor does it even reference the Federal Policy or the HHS policy. To the contrary, GW's policy states as follows:

> **Policy Statement**
> Research misconduct includes, without limitation, fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results. All employees or individuals associated with George Washington University should report observed, suspected, or apparent misconduct in research to the Research Integrity Officer (RIO).
>
> **Reason for Policy/Purpose**
> The research mission of the university is to create and synthesize knowledge at the frontiers of our understanding and to use that knowledge to address issues of increasing complexity in our world, while strengthening the necessary ties between teaching and research. In pursuing this mission, the university seeks to promote

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[9] *See infra* n.13.

> and to conform to the highest standards of ethical research and scholarly conduct.

See The George Washington University Policy and Procedures Regarding Allegations of Research Misconduct ("GW Policy") (attached hereto as Exhibit A) at p. 1. The scope of the Policy is quite broad, as it applies to anyone conducting research at or connected to GW:

> This policy and the associated procedures apply to all individuals at GW engaged in research, research-training or research-related grants, contracts, or other agreements. More specifically, this policy applies to any person paid by, under the control of, or affiliated with GW, such as faculty, scientists, trainees, technicians and other staff members, students, fellows, guest researchers, or collaborators at or with GW.

GW Policy at §I(B). GW's Policy applies to *all* research – whether or not it is federally funded and whether or not it is biomedical or behavioral research (the only type of research to which the HHS regulations apply).[10] Application of the policy as a whole is not constrained to allegations involving federally funded research. Although some provisions apply only to external "funders"[11] and a few provisions apply exclusively to HHS funded research, all other provisions – including those about which Dr. Kumar complains – apply equally to research that was not federally funded. In contrast, ORI's authority only extends to federally funded scientific research. There are only a few provisions in the policy that apply only where HHS funded research is involved.[12] Dr. Kumar's allegations do not assert violations of any such provisions.

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[10] 42 C.F.R. §§93.100(b), 93.102(a), (b).

[11] *See* GW Policy at §§V(D), VIII(F), XII.

[12] These are the provisions requiring GW to comply with its regulatory obligations to report to ORI (Exhibit A at §II(A)); the provision imposing a 30 day deadline for submission of a *complainant's* comments to the draft investigation report (Exhibit A at §VII(A)(2)); the provision requiring that the final report and decision of the Provost be submitted to ORI (Exhibit A at §VII(B), (D)) within 120 days of the first meeting of the investigation committee (Exhibit A

All of Dr. Kumar's allegations pertain to the GW Policy provisions that apply equally to all kinds of research (whether externally funded or not). Moreover, GW's Policy includes fifteen defined terms and other than the definitions of "PHS regulation" and "PHS support," none of them even refer to the federal regulations.[13] Nor does GW's Policy apply only to allegations of misconduct in biomedical or behavioral research (as does the HHS policy)[14] – it applies to research of any kind. If this Court were to grant GW the immunity it seeks, then Dr. Kumar would be deprived of the ability to challenge the manner in which GW conducted the investigation and to challenge the employment and other adverse decisions made by GW, while other researchers at GW would not be so deprived and would have full access to the courts to address any claims.

III. THE DECISIONS ABOUT WHICH DR. KUMAR COMPLAINS DO NOT CONSTITUTE A DISCRETIONARY FUNCTION

GW has also failed to demonstrate another essential component of government immunity – that the research misconduct investigation which underlies Dr. Kumar's claims is a "discretionary" function. GW attempts to show that the investigation is quintessentially

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(footnote continued)

at §VII(E)); the provision establishing reporting requirements to ORI (Exhibit A at §VIII); the provision requiring GW to restore the reputation of a respondent found not to have engaged in research misconduct (Exhibit A at §XI(B)); the provision giving ORI or other HHS personnel access to files after completion of a case (Exhibit A at §XII).

[13] GW will no doubt respond that its misconduct policy complies with the federal regulations. It may well comply with the regulations, but the policy is also more expansive and is not limited to federally funded research. The fact that the policy complies with the regulations does not show that the implementation of the policy is a delegated government function or that conducting investigations pursuant to the policy is a "discretionary function" warranting immunity.

[14] *See* 42 C.F.R. §93.102.

discretionary because of various judgments that have to be made during an investigation.[15] Any facial appeal of the contention that investigations require a whole host of decisions and therefore are "discretionary" is fleeting at best and cannot withstand the analysis that must be applied to it.

In *Berkovitz v. United States*, 486 U.S. 531 (1988) (relied on by GW at page 3 of its Memorandum), the Supreme Court examined the discretionary function standard under the Federal Tort Claims Act in the context of injuries arising from polio vaccine injections. The Court "specifically [ ] reject[ed] the Government's argument . . . that exception precludes liability for any and all acts arising out of the regulatory programs of federal agencies." 486 U.S. at 538. The Court held that the "discretionary function exception applies only to conduct that involves the permissible exercise of policy judgment." 486 U.S. at 539. Citing *Berkowitz*, GW contends its actions are immune because ORI regulations confer institutions such as GW with discretion in investigating research misconduct. GW's Memo. at 4. GW contends that some of Dr. Kumar's claims involve GW's regulatory obligations to take "reasonable steps" to ensure impartial and unbiased investigations (required by 42 C.F.R. §93.31(f)) by empaneling an investigation committee that is not biased or conflicted, and GW's regulatory obligations (under 42 C.F.R. §93.108(a)) to keep the identity of the respondent limited to those who need to know. According to GW, the foregoing satisfies the requirement in *Berkowitz* that the challenged action must be "the product of judgment or choice." GW's Memo. at 3-4.

Besides the fact that GW ignores the totality of Dr. Kumar's First Amended Complaint and focuses on just two contentions, GW is analyzing operational decisions, not policy

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[15] The Court need not resolve whether the investigation was or was not a discretionary function because, as the first part this opposition demonstrates, GW has failed to establish that it is otherwise entitled to immunity. However, because GW briefly addresses this issue in its short Memorandum, Dr. Kumar is responding to the argument.

decisions.[16] Even a government agency (for example, ORI) conducting an investigation in the manner in which GW did would not enjoy immunity under these circumstances. That is because the discretionary function doctrine looks at *policy* decisions, not operational decisions. *See Hendry v. United States*, 418 F.2d 774, 783 (2nd Cir. 1969) (government was not immune where plaintiff was complaining about the "way in which the Coast Guard and the Public Health Service applied medical principles to his case, not of the content of the principles which they adopted as relevant"); *White v. United States*, 317 F. 2d 13 (4th Cir. 1963) (government not immune from claims arising from suicide of plaintiff's decedent who was under the care of a Veteran's Hospital); *Liuzzo v. United States*, 508 F. Supp. 923 (E.D. Michigan 1981) (government not immune from claims that FBI agents and an FBI informant engaged in negligent and wrongful acts which proximately caused plaintiffs' mother's death).[17]

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[16] Dr. Kumar acknowledges that in *United States v. Gaubert* the Supreme Court rejected a bright-line rule making application of the discretionary function exception dependent solely on whether the actor was an operational level employee or a policy level employee. 499 U.S. 315, 325 (1991). Even under *Gaubert*, however, to be protected by the discretionary function exception, the decisions and conduct involved must be based on policy. 499 U.S. at 325-26. As Justice Scalia noted in his concurring opinion, although no bright line rule applies, "the level at which the decision is made is often *relevant* to the discretionary function inquiry, since the answer to that inquiry turns on *both* the subject matter *and* the office of the decisionmaker." 499 U.S. at 335 (Scalia, J., concurring) (emphasis in original). *See Cope v. Scott*, 45 F.3d 445, 448 (D.C. Cir. 1995) (under *Gaubert*, "[o]nly discretionary actions of greater significance —those grounded in "social, economic, or political goals"— fall within the protection of the statute").

[17] The analysis used in these older cases which focused on implementation versus planning remains valid even after the Supreme Court's decision in *United States v. S.A. Empresa De Viacao Aerea Rio Grandense,* 467 U.S. 797 (1984) ("*Varig Airlines*") (one of the cases cited by GW at p.2 of its Memorandum). As explained by *Leone v. United States*, 690 F. Supp. 1182 (E.D.N.Y. 1988), although *Varig Airlines* include some very broad language, its precise holding still depended on a finding that the decision at issues involved a policy decision. *Leone*, 690 F. Supp. at 1187-88. The court noted that decisions "like those in *Hendry* that do not involve policy judgments are not protected by the discretionary function exception." 690 F. Supp. at 1188. *See also Whisnant v. United States*, 400 F.3d 1177, 1183 (9th Cir. 2005) (where decision

In *Cope v. Scott*, 45 F.3d 445 (D.C. Cir. 1995), the D.C. Circuit found that the arguments of both the Government and the plaintiff were too broad because each urged the application of a bright line rule. The government, much like GW here, argued the discretionary function exception applies every time a decision "involve[s] choice and the faintest hint of policy concerns[.]" 45 F.3d at 449. As cautioned by court, such an approach "would not only eviscerate the second step of the analysis set out in *Berkovitz* and *Gaubert*, but it would allow the exception to swallow the FTCA's sweeping waiver of sovereign immunity. . . . The mere presence of choice—even if that choice involves whether money should be spent—does not trigger the exception." *Cope*, 45 F.3d at 449. The *Cope* Court also rejected the plaintiff's reliance on a bright line rule which would always reject application of the exception where implementation of a policy decision was at issue. *Id.* The Court stated the proper analytical approach as follows: "No matter the level at which the decision was made, the nature of the decision, or the impact it had on others, we have consistently held that the discretionary function exception applies 'only where the question is not negligence but social wisdom, not due care but political practicability, not reasonableness but economic expediency.'" 45 F.3d at 450 (quoting *Sami v. United States*, 617 F.2d 755, 766 (D.C. Cir. 1979)) (additional internal quotations omitted). Applying its analysis to the case before it, the Court rejected the government's claim that its decisions regarding the posting of warning signs about the surface conditions of Beach Drive fell within the discretionary function exception. 45 F.3d at 451-52. Because the applicable manual provided that it was not a substitute for "engineering judgment" and that warning signs should be posted only where it was "deemed necessary," the Court agreed with the

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(footnote continued)

to adopt safety measures may be based on policy decision, but the implementation is not, the way in which the decision is implemented is not protected).

government that the posting of signs involved the exercise of discretion. *Id.* at 451. However, the Court did not agree that such decisions involved the type of discretion protected by the discretionary function exception. *Id.* The Court explained:

> While it may be true, as the government claims, that the placement of signs involves judgments because engineering and aesthetic concerns determine where they are placed, such judgments are not necessarily protected from suit; only if they are "fraught with public policy considerations" do they fall within the exception, and we do not think that is the case here. The "engineering judgment" the government relies on is no more a matter of policy than were the "objective scientific principles" that the *Berkovitz* court distinguished from exempt exercises of policy judgment. *See* 486 U.S. at 545, 108 S.Ct. at 1963.

45 F.3d at 451-52.

In *White*, the regulations of the Veteran's Administration stated the policy that psychiatric patients should be allowed the maximum independence permitted by their conditions. 317 F.2d at 15. The Virginia veteran's hospital where the decedent was receiving care had four levels of permitted freedom, ranging from privileged (permitting patients free access to hospital grounds) to locked. 317 F.2d at 15. Classification decisions were made by staff physicians at the time of admission, but a patient could be moved to a more secure classification if a staff physician determined that move was warranted by circumstances. 317 F.2d at 15. The decedent had been on observation/locked ward status, but was transferred to privileged status five days before his suicide. 317 F.2d at 15. On the day of his death, the patient had complained of apprehension and nervousness and the on-duty physicians increased his tranquilizer dose and administered a sedative. 317 F.2d at 16. Neither physician was familiar with the decedent's background medical history. 317 F.2d at 16. The government argued that it should be immune from the estate's negligence claim, reasoning that the decision of the degree of freedom to accord the decedent was a discretionary function. 317 F.2d at 17. The Court rejected the government's

immunity claim explaining that a distinction must be drawn between the discretion which factors into making policy decisions, and the discretion which factors into implementing policy decisions:

> While the policy embodied in the Veterans Administration Regulations that patients should be allowed the maximum of freedom warranted by their condition is a discretionary decision, the application of that policy to an individual case is not within the category of policy decisions exempted by the statute. The application of that policy to the individual case is an administrative decision at the operational level which if negligently done will make the Government liable — whether it involves substandard professional conduct (malpractice) or simple negligence in custodial care.

317 F.2d at 17. *See also Liuzzo*, 508 F. Supp. at 931-32 (no immunity where plaintiffs' claims were based on the manner in which the government implemented its policy on using informants, rather than on the government's decision to use informants and its formulation of policies regarding the recruitment, training and supervision of informants). In *Whisnant v. United States*, 400 F.3d 1177, 1183 (9th Cir. 2005), where the plaintiff did not allege the government was negligent in designing safety inspection procedures but rather was negligent in failing to follow-through on the safety procedures to safeguard the health of the employees or customers, the government's decisions were not covered by the discretionary function exception even if those decisions were impacted by cost and budgetary considerations. 400 F.3d at 1183. The court stated: "In this case, Whisnant has alleged negligence in the implementation, rather than the design, of government safety regulations, and the governmental decisions Whisnant claims were negligent concerned technical and professional judgments about safety rather than broad questions of social, economic, or political policy. Therefore, the discretionary function exception to the FTCA does not bar Whisnant's suit." 400 F.3d at 1185.

Here, while the government's policy decision that allegations of misconduct in conducting research funded with federal monies should be investigated may be a discretionary policy making decision for the government, the manner in which GW, as an individual university, conducts an investigation in an individual case is not a function that is protected by immunity because GW is not making policy decisions.

GW acknowledges that immunity will not be conferred unless the challenged action was based on "considerations of social, economic, and political policy." GW's Memo. at 3 (citing *Berkovitz*, 486 U.S. at 536-37). GW asserts that this prong is satisfied by the "social and economic considerations in the protection of federal funds and research integrity." GW's Memo. at 4.[18] Dr. Kumar does not disagree with the notion that the government's decision that allegations of research misconduct should be investigated as a way to promote research integrity and protect federal funds was a decision based on social policy.[19] However, that does little to advance GW's argument because ***GW's*** misconduct policy (which is the policy at issue here) makes no statement regarding considerations of *federal* social, economic or political policy.

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[18] GW cites to *Responsibilities of Awardee & Applicant Institutions for Dealing With & Reporting Possible Misconduct in Science*, 54 Fed. Reg. 32446 (1989), which is 42 C.F.R. Part 50, subpart A. GW's Memo. at 4. As noted by HHS's Policy, that subpart was withdrawn and replaced with Part 93 (the HHS Policy). 70 Fed. Reg. 28370.

[19] It is not as clear that the decision was driven by "economic" policy. The same Federal Register publication cited by GW notes that in the financial impact analysis that a "regulatory impact analysis be prepared for 'major' rules which are defined in the [Executive] Order as any rule that has an annual effect on the national economy of $100 million or more, or certain other specified effects. The PHS does not believe that this regulation will have an annual economic impact of $100 million or more or the other effects listed in the Order. For this reason, the PHS has determined that this regulation is not a major rule within the meaning of the Order." 54 Fed. Reg. 32446, 32448 (Aug. 8, 1989).

IV. GW'S ACTIONS WERE OUTSIDE THE REGULATIONS

GW's Motion should be denied for the additional reason that none of Dr. Kumar's claims are based on violations of the regulations.[20] Rather, they are based on violations of GW's Misconduct Policy, GW's Faculty Code, GW's retaliatory actions, and on the adverse employment decisions that GW made as a result of the botched investigation. GW, like the Port Authority in the *McCue* case, has not cited to any regulation "that required it to engage in the precise actions of which Plaintiff[] complain[s]." 521 F.3d at 200. As alleged in the First Amended Complaint, GW used the research misconduct investigation to essentially conduct a performance review of Dr. Kumar in his capacity as a professor and department chair. FAC at ¶¶68-70. GW's appointment letter, reappointment letters and various policies, including the research misconduct policy and the Faculty Code, constituted a contract between Dr. Kumar and GW. FAC at ¶¶8-10, 14, 15, 127. In Count I, Dr. Kumar alleges that GW breached its contract by its various actions, including violating Dr. Kumar's contractual right to have the misconduct investigation conducted in a fair manner; violating Dr. Kumar's contractual rights as a tenured professor; violating Dr. Kumar's contractual rights to have access to his laboratory and his scientists; violating Dr. Kumar's contractual rights to have his compensation determined and adjusted in a particular manner. In Count II, Dr. Kumar alleges that GW breached the covenant

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[20] Some of the allegations in the First Amended Complaint refer to violations of both GW's own policies and the federal regulations. *See e.g.*, FAC at ¶¶72, 112, 121. This is because parts of GW's research misconduct policy are necessarily drafted in a manner to comply with its regulatory obligations and therefore some of the breaches of GW's misconduct policy also constitute violations of the regulations. However, Dr. Kumar's claims expressly allege violations of GW's research misconduct policy which applies to *all* GW faculty and other personnel engaged in research, whether federally funded or not. Indeed, it is GW's policies, not the federal regulations, which constitute the contract between Dr. Kumar and GW.

of good faith and fair dealing implied in its contracts with GW. GW has not cited any cases which arise in the context of claims for breach of contract and breach of covenant of good faith and fair dealing claims and which entitle GW to immunity in that context. Governmental immunity, at best, is immunity from tort claims, not from contractual claims. For this reason alone Counts I and II must survive GW's Motion to Dismiss based on immunity.

GW's motion should be denied even as to the tort claims (Counts III through V) because those claims are based on actions GW took outside of the investigation itself. GW forced Dr. Kumar to step down as the Department and McCormack Chair; wrongly replaced Dr. Kumar as the credited faculty member for a Ph.D candidate's thesis; interfered with Dr. Kumar's employment opportunities; violated Dr. Kumar's rights as a tenured faculty member by denying him access to the building, his staff and his office; it disclosed confidential information; and it publicly humiliated Dr. Kumar by having him escorted out of his laboratory and forbidding him from communicating with his scientists. Clearly none of these were delegated government functions. None of those personnel decisions were delegated to GW by the government. To allow GW to engage in this whole host of tortious activity and then hide behind the shield of government immunity would be unfair and contrary to the purposes of governmental immunity.

GW also contends that Dr. Kumar's "allegations of bad faith[21] must be dismissed since the underlying motives for the conduct are irrelevant to the official immunity analysis." GW's Memo. at 4 (citing *Walkwell Int' Labs., Inc. v. Nordian Admin. Servcs. LLC*, No. 1:13-cv-0199-

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[21] The only allegations of "bad faith" are made in Count II for breach of the covenant of good faith and fair dealing implied in its contractual relationship with Dr. Kumar. As explained above, GW has offered no legal authority supporting dismissal of a good faith and fair dealing (which is grounded in contract) on immunity grounds. To the extent that GW meant to also refer to the allegations of evil motive, actual malice, intent to injure and willful disregard in Counts III through V, GW's request for dismissal must be denied because for all the reasons set forth herein, GW has not otherwise established that it is entitled to immunity from those claims.

EJL-REB, 2014 WL 174948, at *9 (D. Idaho Jan. 13, 2014)) (footnote added). It is correct that bad faith motives cannot defeat an otherwise properly established immunity defense. Here, however, GW has failed to demonstrate that it is entitled to immunity from Dr. Kumar's claims.

CONCLUSION

For all the foregoing reasons, Dr. Kumar respectfully requests this Court to deny GW's Motion to Dismiss in all respects.

Dated: July 17, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 17th day of July, 2015, a copy of the foregoing Plaintiff's Opposition to Motion to Dismiss and proposed Order, was served through the Court's CM/ECF system on:

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