UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
LOUISVILLE DIVISION

UNITED STATES OF AMERICA *ex rel.* KAREN BRINKLEY and CAROL WHETSTONE, KAREN BRINKLEY, in her individual capacity, and CAROL WHETSTONE, in her individual capacity Plaintiffs, v. UNIVERSITY OF LOUISVILLE, UNIVERSITY OF LOUISVILLE FOUNDATION, INC., UNIVERSITY OF LOUISVILLE RESEARCH FOUNDATION, INC., DR. ARUNI BHATNAGAR, DR. ROBERTO BOLLI, DR. GEOFFREY CLARK, DR. HENRY KAPLAN, DR. LESLIE SHERWOOD, DR. CHARLES SCOGGINS, DR. ZHAO-HUI SONG, CHERI HILDRETH, individually, and in her capacity as UNIVERSITY OF LOUISVILLE DIRECTOR OF ENVIRONMENTAL HEALTH AND SAFETY Defendants.	)	Civil Action No. 3:15-cv-180-DJH

FALSE CLAIMS ACT FIRST AMENDED COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

Plaintiffs-relators allege as follows:

PARTIES

1. *Qui Tam* plaintiff-relator Karen Brinkley (hereinafter "Brinkley" if referred to individually) is a citizen of the United States of America and a citizen and resident of the Commonwealth of Kentucky. Brinkley began employment with Defendant University of Louisville on or about January 4, 1999 and was employed by Defendant University of Louisville as a Biological Safety Specialist until about December 2014. Brinkley brings this action, in conjunction with Carol Whetstone, as Plaintiffs-relators on behalf of the United States of America pursuant to 31 U.S.C. §3730(b)(1) and individually pursuant to 31 U.S.C. §3730(h), KRS 61.102, KRS 61.990, and the common law.

2. *Qui Tam* plaintiff-relator Carol Whetstone (hereinafter "Whetstone" if referred to individually) is a citizen of the United States of America and a citizen and resident of the Commonwealth of Kentucky. Whetstone began employment with Defendant University of Louisville on or about November 5, 2001 and was employed by Defendant University of Louisville as the Institutional Biological Safety Officer until about December 2014. Whetstone brings this action, in conjunction with Brinkley, as Plaintiffs-relators on behalf of the United States of America pursuant to 31 U.S.C. §3730(b)(1) and individually pursuant to 31 U.S.C. §3730(h), KRS 61.102, KRS 61.990 , and the common law.

3. Pursuant to 31 U.S.C. § 3730(b)(2), at the time of filing of this Complaint, Plaintiffs-relators shall provide to the United States Attorney for the Western District of Kentucky a statement of all material evidence and information related to this Complaint.

4. The United States of America is a named plaintiff by this action because Defendants fraudulently obtained funds of the United States of America as alleged herein.

5. Defendant University of Louisville ("UL") is a publicly funded Kentucky university that is comprised of a number of undergraduate and graduate units with its principal place of business at the Office of University Counsel, University of Louisville, Louisville, KY 40292 In addition to the education of students, UL also funds and conducts scientific research that is largely funded by federal grants.

6. Defendant University of Louisville Foundation, Inc. ("ULF") is a Kentucky foundation affiliated with UL that funds and conducts scientific research that is largely funded by federal grants. ULF's principal place of business is 103 Grawemeyer Hall, University of Louisville, Louisville, KY 40292.

7. Defendant University of Louisville Research Foundation, Inc. ("ULRF") is a Kentucky foundation affiliated with UL that funds and conducts scientific research that is largely funded by federal grants. ULRF's principal place of business is at the Office of University Counsel, University of Louisville, Louisville KY 40292.

8. Defendants UL, ULF, and ULRF are herein collectively referred to as "Louisville Defendants."

9. To the best of Plaintiffs-relators' knowledge, Defendant Aruni Bhatnagar is a Kentucky resident and was an employee of and/or researcher for the Louisville Defendants' and was listed as the Principal Investigator ("PI") on numerous government grant applications during the relevant times listed below. Defendant Bhatnagar also conducted and/or oversaw research for Louisville Defendants.

10. To the best of Plaintiffs-relators' knowledge, Defendant Roberto Bolli is a Kentucky resident and was an employee of and/or researcher for the Louisville Defendants' and was listed as the Principal Investigator ("PI") on numerous government grant applications during the relevant times listed below. Defendant Bolli also conducted and/or oversaw research for Louisville Defendants.

11. To the best of Plaintiffs-relators' knowledge, Defendant Geoffrey Clark is a Kentucky resident and was an employee of and/or researcher for the Louisville Defendants' and was listed as the Principal Investigator ("PI") on numerous government grant applications during the relevant times listed below. Defendant Clark also conducted and/or oversaw research for Louisville Defendants.

12. To the best of Plaintiffs-relators' knowledge, Defendant Henry Kaplan is a Kentucky resident and was an employee of and/or researcher for the Louisville Defendants' and was listed as the Principal Investigator ("PI") on numerous government grant applications during the relevant times listed below. Defendant Kaplan also conducted and/or oversaw research for Louisville Defendants.

13. To the best of Plaintiffs-relators' knowledge, Defendant Leslie Sherwood is a Kentucky resident and was an employee of and/or researcher for the Louisville Defendants' and was listed as the Principal Investigator ("PI") on numerous government grant applications during the relevant times listed below. Defendant Sherwood also conducted and/or oversaw research for Louisville Defendants.

14. To the best of Plaintiffs-relators' knowledge, Defendant Charles Scoggins is a Kentucky resident and was an employee of and/or researcher for the Louisville Defendants' and was listed the Principal Investigator ("PI") on numerous government grant applications during the relevant times listed below. Defendant Scoggins also conducted and/or oversaw research for Louisville Defendants.

15. To the best of Plaintiffs-relators' knowledge, Defendant Zhao-Hui Song is a Kentucky resident and was an employee of and/or researcher for the Louisville

Defendants' and was listed as the Principal Investigator ("PI") on numerous government grant applications during the relevant times listed below. Defendant Song also conducted and/or oversaw research for Louisville Defendants.

16. To the best of Plaintiffs-relators' knowledge, Defendant Cheri Hildreth is a Kentucky resident and at times relevant to this Complaint was the UL Director of the Department of Environmental Health and Safety. In her capacity as director, Defendant Hildreth oversaw and/or was responsible for various research applications, proper usage of government funds, including but not limited to Facilities and Administrative (F&A) funds provided through grant funding, and/or that research was conducted in accordance with the applicable terms and conditions.

JURISDICTION AND VENUE

17. Plaintiffs-relators incorporate by reference and re-allege the allegations contained in Paragraphs 1 through 16 as if fully set forth herein.

18. This action is brought pursuant to the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* and subject matter jurisdiction is proper pursuant to 28 U.S.C. § 1331, which confers general subject matter jurisdiction; pursuant to 31 U.S.C. § 3732, which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C §§ 3729 and 3730; and, pursuant to 28 U.S.C. § 1345 because the United States of America is a named plaintiff.

19. This Court has jurisdiction over the Kentucky statutory claims and common law claims pursuant to 28 U.S.C. § 1367(a) as the claims are so related to the actions arising pursuant to 31 U.S.C. § 3730(h) that they form part of the same case or controversy because they arise from the same set of operative facts.

20. This court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because Defendants can be found, reside, or transact business in this District. In addition, Defendants engaged in acts proscribed by 31 U.S.C § 3729 in this District.

21. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391 as the acts complained of herein occurred in this District and Defendants reside in this District.

22. This suit is not based upon prior public disclosures of allegations or transactions in a federal criminal, civil, or administrative hearing, lawsuit, or investigation, or in a government Accounting Office or Auditor General's report, hearing, audit, or investigation, or from the news media.

23. To the extent that there has been any public disclosure unknown to plaintiff-relators, plaintiff-relators are original sources under 31 U.S.C. § 3730(e)(4).

Plaintiff-relators have voluntarily disclosed to the United States the information on which the allegations herein are based and/or have voluntarily provided to the United States direct and independent knowledge that materially adds to any publicly disclosed allegations or transactions upon which these claims are based prior to filing an action under this section.

INTRODUCTION

24. Plaintiffs-relators incorporate by reference and re-allege the allegations contained Paragraphs 1 through 23 as if fully set forth herein.

25. This is an action to recover treble damages and civil penalties on behalf of the United States of America arising out of false claims presented by Defendants to the United States in violation of 31 U.S.C. § 3729, to recover compensatory and punitive damages for violations of 31 U.S.C. § 3730, and to recover compensatory and punitive damages for violations of KRS 61.102, KRS 61.990, and the common law.

Federally Funded Research and the Defendants' Receipt Thereof

26. Each year the United States funds millions of dollars of research for the common good. Given the great public trust in the results of government funded research, the government has a strong interest in ensuring it is funding objective scientific data and that government funded research is performed according to the proper standards and requirements. Consequently, federally funded research requires full compliance with the terms of grant funding as well as applicable laws, regulations, and policies. Compliance is central to research funding and is an integral part of federally funded research.

27. From at least 2008 and continually through the present, Defendants have obtained millions of dollars from the National Institutes of Health ("NIH"), the United States Department of Defense ("DOD"), and other Federal agencies (collectively referred to hereinafter as the "Government") in grant funding.

28. To apply for and receive federal NIH grants, Louisville Defendants are the grantee institutions that actually receive, spend, and/or oversee the use of funds provided by the United States. Louisville Defendants must have a specific researcher agree to serve as each grant's PI. The PI is an individual designated by the grantee to direct the project or activity being supported by the grant. He or she is responsible and accountable to the grantee and the grant's issuing agency for the proper conduct of the project or activity.

29. Each year researchers affiliated with and/or employed by Louisville Defendants apply for and receive millions of dollars in grants from the Government, specifically, and from the United States, generally.

30. In order to receive its extensive and ongoing grant funding, Defendants submitted numerous grant applications to the Government. Those grant applications contained detailed information about the grantee institution, the grant's PI(s) and other contributing personnel, an overview of the research or project for which funding is sought, the resources and support provided by the grantee institution, and a comprehensive budget.

31. Prior to the receipt of any funds from the Government and/or beginning any research, Defendants submitted, or were supposed to submit, completed applications to the UL Institutional Biosafety Committee ("IBC") to ensure that research would be conducted in accordance with the Government's stated terms and conditions. In their capacity as Biological Safety Specialist and Biological Safety Officer, Plaintiffs-relators served in a support role with respect to the IBC and assisted with application review.

32. As part of the Government approval and award process, the Government requires that grantees and their respective grantee institutions accept specific terms and conditions prior to the receipt of grant funds. Those terms and conditions explicitly include compliance with applicable federal and state laws and regulations as well as compliance with the NIH Grant Policy Statement ("NIHGPS") and NIH Guidelines, including the NIH Guidelines for Research Involving Recombinant Synthetic Nucleic Acid Molecules ("NIH Guidelines").

33. Defendants were specifically aware of the potential loss of funding or the imposition of additional conditions. By way of example, Defendants explicitly acknowledged that continued funding was contingent upon regulatory compliance. *See* December 20, 2006 Notice to All Faculty and Staff Working With Biological Agents and/or Recombinant DNA attached hereto as **Exhibit A**.

34. Upon information and belief, at all times mentioned herein, Defendants had and continue to have actual knowledge that they were not in compliance with the applicable statutes, regulations, guidelines, and/or policies applicable to the grant funding received, that their implicit and explicit representations of compliance were and/or are false and that they were submitting false and/or fraudulent representations of compliance. Alternatively, Defendants acted and/or continue to act with deliberate indifference and/or reckless disregard as to the truth or falsity of their claims.

The NIH Grants Policy Statement, Related Grant Requirements, and Required Certifications of Compliance

35. NIH grant applications and all other Applications for Federal Assistance ("Form SF 424"), including each of the grant applications referenced herein, contain the following certification statement (hereinafter referred to as the "Application Certification"):

> By signing this application, I certify (1) to the statements contained in the list of certifications and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements of claims may subject me to criminal, civil, or administrative penalties (U.S. Code Title 218, Section 1001).

A sample copy of the standard form is attached as **Exhibit B**.

36. A Notice of Award letter accompanies all NIH Grants and its terms are explicitly conditions of the grant. The introduction to the Notice of Award letter, including the Notice of Award Letters referenced herein, provide, in part, as follows:

> This award is pursuant to the authority of 42 U.S.C. 241 [and] 42 CFR. 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.
>
> Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

A sample of the Notice of Award is attached hereto as **Exhibit C**.

37. Section III of NIH Notice of Award letters, including but not limited to the Notice of Award Letters referenced herein, provide, in part, as follows:

> This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:
>
> a. The grant program legislation and program regulation cited in this Notice of Award.
>
> b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
>
> c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.

d. The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.

e. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

See attached **Exhibit C.**

38. The NIHGPS specifically states, in part, that:

> Program and administrative policies and the terms and conditions of individual awards are intended to supplement, rather than substitute for, governing statutory and regulatory requirements. Thus, the requirements of the NIHGPS apply in addition to governing statutory and regulatory requirements not cited herein, and award-specific terms apply in addition to the requirements of the NIHGPS.

NIHGPS, Part II: Terms and Conditions of NIH Grant Awards, Page IIA-1. A true and correct copy of the relevant portion of the NIHGPS is attached as **Exhibit D**.

39. As part of the NIH requirements, grantee institutions are specifically expected to "provide safe and healthful working conditions for their employees and foster work environments conducive to high-quality research." *NIHGPS*, Part II: Terms and Conditions of NIH Grant Awards, Page IIA-3. See attached **Exhibit D.** These safety standards are explicitly tied to and are a primary condition of the expenditure of funds as the NIH "intends to uphold high ethical, health, and safety standards in both the conduct of the research it funds and the expenditure of public funds by its grantees." *NIHGPS*, Part II: Terms and Conditions of NIH Grant Awards, Page IIA-3. See attached **Exhibit D.**

40. In addition, the NIHGPS specifically makes ongoing compliance with the above referenced guidelines and regulations a condition of payment by collectively stating, in part, that:

> [I]f the inclusion of the term or condition would cause the grantee not to accept the award or to be unable to comply, the question should be raised before funds are requested from the HHS payment system. By drawing funds from the HHS payment system, the grantee agrees to the terms and conditions of the award.

NIHGPS, Part II: Terms and Conditions of NIH Grant Awards, Page IIA-2. See attached **Exhibit D**.

41. As part of those conditions grantees are explicitly "responsible for meeting applicable Federal, State, and local health and safety standards and for establishing and implementing measures to minimize their employees' risk of injury or illness in activities related to NIH grants." *NIHGPS*, Part II: Terms and Conditions of NIH Grant Awards, Page IIA-21. See attached **Exhibit D**.

42. Moreover, those duties are explicitly continuing in nature, as:

> A grantee indicates acceptance of an NIH award and its associated terms and conditions by drawing or requesting funds from the designated HHS payment system or office. If the grantee cannot accept the award, including the legal obligation to perform in accordance with its provisions, it should notify the GMO immediately upon receipt of the NoA.

NIHGPS, Part II: Terms and Conditions of NIH Grant Awards, Page IIA-44. See attached **Exhibit D**.

43. Funds paid to a grantee at any time during the life cycle of a grant that are used for an improper purpose and/or other unapproved usage may be recovered by the Government and constitute debts to the United States. These debts are specifically acknowledged, for example, by the NIHGPS, which states, in part, that:

> NIH may identify and administratively recover funds paid to a grantee at any time during the life cycle of a grant. Debts may result from cost disallowances, recovery of funds, unobligated balances, unpaid share of any required matching or cost sharing, funds in the recipient's account that exceed the final amount determined to be allowable, or other circumstances. NIH may identify and initiate debt collection activities at any time during the life cycle of a grant.

NIHGPS, Part II: Terms and Conditions of NIH Grant Awards, Page IIA-118. See attached **Exhibit D**.

44. In addition to the requirements listed above, Defendants submitted numerous other certifications of compliance to the Government. These certifications included but were not limited to initial and continuing review records of the IBC, consent forms, financial Service Requests, and adequate and accurate study records.

45. Consistent with the statutory and regulatory framework of the Government and/or NIH grant policies any and all NIH funded research must meet, at a minimum, the requirements listed herein. Similarly, any and all NIH funded research requires, at a minimum, the certifications listed herein. Accordingly, all research and/or grants

referenced herein constitute examples of a larger class of certifications easily identifiable by Defendants.

46. In addition to compliance and reporting requirements placed upon grantee institutions, the participating researchers and principle investigators are fully responsible for reporting non-compliance to the Government under NIH Guideline Section IV-B-7. Accordingly, at all times up to and after the receipt of federal funds, all Defendants had an affirmative duty to comply with NIH Guidelines and/or to notify the government of non-compliance.

47. Usage of federal funds for unauthorized and/or non-compliant activities constitute unallowable charges and adjustments must be made to the grant to remove those charges. NIH Guidelines specifically require that reports contain a certification that no unallowable costs were charged to NIH grant funds during a period of noncompliance.

Defendants' General Failure to Comply with the NIH Grants Policy Statement and Related Grant Requirements

48. Via submission of grant applications, including but not limited to the applications referenced herein, the Application Statements contained therein, and the acceptance of funds from the United States upon receipt of the Notice of Awards, Defendants explicitly and/or implicitly certified to the Government that they had complied and/or would continue to comply with the Government's terms and conditions including but not limited to the compliance with applicable laws, regulations, and/or the NIHGPS.

49. Receipt of grant funding is contractual in nature and the certification of prior and ongoing compliance with the applicable statutes, regulations, guidelines, and/or policies was an explicit term of the contract and a prerequisite to grant funding. Accordingly, the certification of past and future compliance is a condition of payment and each account draw or other receipt of funds accompanied by any past or future incident of non-compliance constitutes a false statement, claim, and/or certification made to the United States.

50. At all times referenced in this Complaint, Defendants knowingly and/or recklessly failed to have the proper systems, policies, procedures, and/or personnel in place to assure compliance despite ongoing knowledge by Defendants of numerous incidents of non-compliance and general organizational shortcomings. In addition to being aware of these incidents as they occurred and/or at the specific times referenced herein, Defendants were repeatedly informed of non-compliance by Plaintiffs-relators, including but not limited to during May 2014 when Plaintiffs-relators reported numerous NIH and CDC DSAT violations to the UL Vice President of Business Affairs.

51. At all times referenced in this Complaint, Defendants were knowingly and/or recklessly not in compliance and/or knowingly and/or recklessly did not remain in compliance with the applicable statutes, regulations, guidelines, and/or policies.

52. Defendants falsely represented their past and ongoing compliance with the NIHGPS and/or NIH Guidelines and therefore made false certifications and false statements to the Government for the purpose of obtaining federal funds from the United States of America.

53. In addition to making specific false representations and false statements, Defendants turned a blind eye to organizational shortcomings, purposefully underfunded and/or under-supported the compliance department, and/or encouraged the members of the IBC to delay reports or to not report non-compliance and therefore conspired to commit a violation of 31 U.S.C. § 3729.

54. Defendants intended the Government to reply upon their false representations in order to unlawfully obtain funding from the Government. Due to the Defendants' false and fraudulent representations the Government was denied the benefit of its bargain. Had the Government known the true facts, Defendants could and/or would have been denied funding from the Government; the Government could have instituted additional conditions on the receipt of grant funding; and/or the Defendants would have had to refund a portion of grant funding to the Government.

55. By falsely representing their compliance with the NIHGPS statement and NIH Guidelines both during the application process and through ongoing non-compliance, Defendants obtained millions of dollars in federal funding that Defendants were not lawfully entitled to receive.

56. Prior to receiving such funds, Defendants, knowingly, falsely, and fraudulently represented material facts to the Government, including but not limited to, that Defendants were and would remain in compliance with the statutes, regulations, guidelines, and/or policies applicable to grant funding received by Defendants.

57. After receipt of such funds and upon engaging in non-compliance and/or failing to report non-compliance, Defendants, knowingly, falsely, and fraudulently represented material facts to the Government, including but not limited to, that Defendants were and would remain in compliance with the statutes, regulations, guidelines, and/or policies applicable to grant funding received by Defendants.

58. The failure to report the non-compliance referenced herein, as well as the specific failure to have appropriate systems in place, allowed serious risks to public safety to remain hidden, constituted the unauthorized and fraudulent use of federal funds, allowed debts to the United States to go unpaid, and deprived NIH of the ability to take any enforcement action or impose special conditions on the awards referenced herein and/or all future awards.

FALSE CLAIMS AND/OR FRAUDULENT STATEMENTS

59. Plaintiffs-relators incorporate by reference and re-allege the allegations contained in Paragraphs 1 through 58 as if fully set forth herein.

60. Defendants have access to and/or have in their custody or control all of the grant application, notices of award, and associated documentation referenced herein. In addition, Defendants have sole access to and/or have in their sole custody or control additional documentation and/or information related to the allegations herein.

61. In addition to the grants referenced above, the Louisville Defendants received at least $165 million in NIH funded grants since 2012. In 2014 alone, the Louisville Defendants received at least $59 million in NIH grant funding.

Failure to Comply with Proper Pipette/Seropipette Disposal Methods

62. By way of example, Defendant Aruni Bhatnagar submitted a grant application for research funding for the University of Louisville Center for Excellence in Diabetes and Obesity Research on behalf of Defendant University of Louisville. As part of that application process, Defendant Bhatnagar agreed to and signed the Application Certification. This grant application was submitted for a project period of September 26, 2008 through June 30, 2018 and is identified as grant number 2P20GM103492-06.

63. By way of example, the grant application submitted by Defendant Bhatnagar also required submission of University of Louisville Proposal Clearance Form for internal use. This form specifically acknowledges Defendants' explicit approval of all grant applications through the Office of Grants Management or Office of Industry Contracts as well as the necessity of compliance with NIH Guidelines. A true and correct copy of the Proposal Clearance Form for grant number 2P20GM103492-06 is attached hereto as **Exhibit E**.

64. By way of example, on or about August 08, 2013, NIH sent Defendant Bhatnagar a Notice of Award for grant number 2P20GM103492-06 as part of its ongoing funding of the Center for Excellent in Diabetes and Obesity Research project. Defendants agreed to the terms of the Notice of Award and accepted funds from the United States. See attached **Exhibit C**.

65. In addition to the research performed under grant number 2P20GM103492-06, Defendant Bhatnagar and other Cardiology researchers performed extensive research for Defendant Roberto Bolli in the cardiology labs. Defendant Bolli, as the PI and/or grant recipient was ultimately responsible for ensuring compliance with NIH Guidelines by his research staff. In addition to all other certifications and requirements, all grant applications submitted by Defendant Bolli would have

contained the Application Certification and all NIH funds received by Defendant Bolli would have required compliance with NIH Guidelines per the related Notice of Award.

66. On or about August 2011, the researchers for the Cardiology group, including Defendant Bhatnagar were performing research under grant 2P20GM103492-06 as well as other federal grants in the cardiology labs.

67. On or about August 2011, Defendants became aware of, were allowing, and/or were encouraging, and continue to allow and/or encourage researchers for the Cardiology group, including Defendant Bhatnagar, to collect small pipette tips in small plastic beakers and then dump the beakers in large biohazard bag lined boxes for disposal. These items may cause leaks and the Cardiology group uses human derived material.

68. As part of an ongoing problem since 2011, and on or about March 2013, Defendant Bhatnagar's viral vector lab failed to have appropriately set up biosafety cabinets, improperly placed standing vertical pipette decontamination containers outside of biosafety cabinets, improperly disposed seropipettes in biohazard bag-lined burn boxes that could be punctured, improperly taped biohazard bags on the front of the biosafety cabinet, failed to place kill pans [horizontal pans partially filled with 10% bleach for the purpose of decontaminating seropipettes prior to their removal from the biosafety cabinet] inside the biosafety cabinet, improperly used 70% ethanol as a disinfectant, and/or improperly permitted blockage of the grills that recirculate air in the cabinets.

69. In addition to the failure to comply with NIH Guidelines, this method of disposal does not comport with the OSHA Bloodborne Pathogen Standard 29 CFR 1910.1030, UL's model Exposure Control Plan, NIH's model Exposure Control Plan and/or the NIH's Waste Disposal Procedures, which the Cardiology group was required to complete due to the use of human derived material. Failure to comply with the model Exposure Control Plan was reported to UL administrative and management personnel including, but not limited to, the assistant director of Environmental Health and Safety. A true and correct copy of the relevant portion of the OSHA Model Plans and Programs for the OSHA Bloodborne Pathogens and Hazard Communications Standards is attached as **Exhibit F**. A true and correct copy of the relevant portion of the UL and NIH model Exposure Control Plans are attached as **Exhibits G and H**, respectively. A true and correct copy of the relevant portion of the NIH Waste Disposal Guide is attached as **Exhibit I**.

70. The above-referenced failure to follow the model Exposure Control Plan and/or the method of disposal utilized during the conducting of this research generally constituted a violation of the terms and conditions of NIH Guidelines and specifically constituted a violation of NIH guideline Appendix G-II-B-2I and G-II-B-2J, as well as the U.S. Department of Health and Human Services Biosafety in Microbiological and Biomedical Laboratories Biosafety Level 2 Standard

Microbiological Practice A(5, 8), which require disposable needles and syringes to be carefully placed in puncture-resistant containers and which state, in relevant part that "[A5] Policies for the safe handling of . . . pipettes . . . must be developed and implemented. . . . [A8] Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport . . . [and] must be packed in accordance with local, state, and federal regulations." A true and correct copy of the relevant portion of the NIH Guidelines for research involving Recombinant or Synthetic Nucleic Acid Molecules is attached as **Exhibit J**. A true and correct copy of the relevant portion of the Biosafety in Microbiological and Biomedical Laboratories manual is attached as **Exhibit K**.

71. The above-referenced failure to properly dispose of biohazardous material generally constitutes a violation of the U.S. Occupation Safety and Health Administration (OSHA) guidelines and specifically constitutes a violation of the OSHA Bloodborne Pathogens Standard (29 CFR §1910.1030). See attached **Exhibit F**.

72. These methods of disposal and lab safety procedures do not comply with NIH Guidelines and constitute improper lab safety. In addition to numerous violations of the NIH and UL model Exposure Control Plans and/or the Biosafety in Microbiological and Biomedical Laboratories standards, the failure to properly train and supervise laboratory staff is a violation of NIH Guideline Section IV-B-7-d-(2). Both Defendants Bhatnagar and Bolli failed to properly supervise and/or train laboratory staff.

73. In addition, the failure to properly train and oversee laboratory staff in recombinant and/or biohazardous material safety procedures was specifically listed as a concern of NIH in the 2010 Site Inspection Letter. A true and correct copy of the 2010 site inspection letter is attached as **Exhibit L**. In addition to generally depriving the United States of the benefit of its bargain, as explained below, Defendants' failure to report this violation and false certification of compliance with the NIH Guidelines specifically deprived the NIH of the ability to follow up on its previously listed concerns and to take any appropriate action due to continued non-compliance despite the 2010 letter.

Failure to Comply With NIH Guidelines Regarding Full IBC Committee Review of Protocols that Add Genes, Plasmids, and/or Viral Vectors

74. By way of example, on or about 2010 Defendant Geoffrey Clark submitted a grant application for research funding for the "The Role of the RAS Effector Nore1A in Tumor Suppression." This project, number CA133171, was approved and Defendant Clark received ongoing Government funding for this project from 2010 to at least 2014. Compliance with NIH Guidelines was an essential part of this funding. In addition to any and all other certifications implicitly or explicitly submitted to the Government, Defendant Clark submitted the Application

Certification to the Government in order to receive Government Funding. In addition to the submission of the Application Certification, Defendant Clark certified ongoing compliance with NIH Guidelines via the receipt of NIH funds for this research after receipt of the related NIH Notice of Award.

75. By way of example, on or about 2010, Defendant Geoffrey Clark submitted a grant application for research for "Oncopigs as a Better Model for Human Cancer" on behalf of Defendant University of Louisville. This project, number CA153132, was approved and Defendant Clark received ongoing Government funding for this project from 2010 to at least 2013. Compliance with NIH Guidelines was an essential part of this funding. In addition to any and all other certifications implicitly or explicitly submitted to the Government, Defendant Clark submitted the Application Certification to the Government in order to receive Government Funding. In addition to the submission of the Application Certification, Defendant Clark certified ongoing compliance with NIH Guidelines via the receipt of NIH funds for this research after receipt of the related NIH Notice of Award.

76. Beginning on or about August 2011, UL responsible officials and/or biological safety specialists did not require IBC committee review of modifications to IBC protocols that added genes, plasmids, and/or viral vectors and/or UL researchers were not properly submitting modifications to IBC protocols to the IBC for approval.

77. During this time period, Defendant Geoff Clark began adding oncogenes with viral vectors to protocols for his research, including but not limited to the above-referenced projects, without submitting a modification and without receiving IBC approval.

78. These protocols generally fall under Sections III-A to III-E of NIH Guidelines and must be fully reviewed by the IBC according to NIH Guidelines. In addition, Defendant Clark failed to obtain a proper risk assessment as required by NIH Guideline II-A-3. A true and correct copy of the relevant portion of the NIH Guidelines is attached as **Exhibit J**.

79. The failure to obtain prior approval to the conduction of research involving a modification of recombinant material and/or the addition of viral vectors generally constitutes a violation of NIH Guidelines and specifically constitutes a violation of Section III-D's requirements regarding the submission of registration and/or modification documents to the IBC for IBC approval prior to the conduct of any research. Failure to receive approval for the specific modification at issue is also a violation of NIH Guideline Section IV-B-7-a-(1). See attached **Exhibit J**.

80. In addition to the failure to obtain prior approval to the conduction of research involving a modification of recombinant material and/or the addition of viral vectors Defendant Clark routinely failed to follow proper lab safety protocols. On numerous inspections throughout the conduct of the above-referenced research projects, Defendant Clark and researchers under his supervision overfilled sharps

containers, failed to wear lab coats when conducting experiments, including when using the biosafety cabinet, failed to place kill pans in biosafety cabinets, improperly reused gloves, and/or failed to conduct viral vector work exclusively in the biosafety cabinet.

81. These lab safety procedures do not comply with NIH Guidelines and constitute improper lab safety. In addition to numerous violations of the NIH and UL model Exposure Control Plans and/or the Biosafety in Microbiological and Biomedical Laboratories standards, the failure to properly train and supervise laboratory staff is a violation of NIH Guideline Section IV-B-7-d-(2). Defendants Clark routinely, and on an ongoing basis from 2011 to 2014, failed to properly supervise and/or train laboratory staff. See attached **Exhibit J**.

82. In addition, the failure to properly dispose of recombinant and/or biohazardous material was specifically listed as a concern of NIH in the 2010 Site Inspection Letter. See attached **Exhibit L**. In addition to generally depriving the United States of the benefit of its bargain, as explained below, Defendants' failure to report this violation and false certification of compliance with the NIH Guidelines specifically deprived the NIH of the ability to follow up on its previously listed concerns and to take any appropriate action due to continued non-compliance despite the 2010 letter.

Failure to Comply with NIH Guidelines Regarding IBC and IACUC Review of Animal Research Proposals

83. Beginning on or about 2008 and continuing until at least mid-2013, pursuant to an improper agreement by and/or between Cheri Hildreth, the Director of the UL Department of Environmental Health and Safety; Erin Foley, the UL Lab Safety Coordinator; and/or Dr. William King, the UL Director of Research Resource Facilities, only the cover sheet of IACUC animal research proposals had been reviewed in order to expedite animal research approvals. This was a violation of UL chemical safety procedures as well as OSHA Guidelines.

84. Due to the ongoing failure to fully review animal research proposals, numerous chemicals were not declared on the cover sheets and animal research protocols were not appropriately handled or reviewed for years. This specifically resulted in the improper approval of numerous projects including, but not limited to, the research conducted by Defendants Clark and Kaplan. This research was conducted in violation of numerous OSHA guidelines, including but not limited to the OSHA Bloodborne Pathogens Standard. As referenced herein, the failure to fully evaluate and approve animal research protocols is also a violation of the NIH Guidelines.

85. Beginning on or about November 2012, researchers began adding biological hazards to animal protocols that had already received Biosafety office approval.

Louisville Defendants, including but not limited to the IACUC, were aware of the improper protocol changes and permitted them to occur.

86. As a result of the IACUC's ongoing failure to properly review research proposals, NIH funded research was performed by Defendant Henry Kaplan without proper approval and in violation of NIH Guidelines. By way of example, on or about 2010, Defendant Kaplan submitted a grant application for research for "P23H Rhodopsin Mutant Swine Model of Reninitis Pigmentosa" on behalf of Defendant University of Louisville. This project, number 5R21EY020647-02, was approved and Defendant Kaplan received ongoing Government funding for this project from 2011 to at least 2013. Compliance with NIH Guidelines was an essential part of this funding. In addition to any and all other certifications implicitly or explicitly submitted to the Government, Defendant Kaplan submitted the Application Certification to the Government in order to receive Government Funding. In addition to the submission of the Application Certification, Defendant Kaplan certified ongoing compliance with NIH Guidelines via the receipt of NIH funds for this research after receipt of the related NIH Notice of Award.

87. In addition to the failure to receive proper IACUC approval, Defendant Kaplan permitted another researcher to use transgenic pig tissue to transplant into wild-type pigs. The other researcher did not have an IBC registration to cover this type of work and, upon information and belief, did not receive proper IBC approval in violation of NIH Guideline III-D-4-b. See attached **Exhibit J**. The failure to properly register this research eventually led to a report to the NIH for non-compliance.

88. Moreover, Defendant Kaplan's work entailed injecting the eyes of pigs with virus and the IBC approved the work to be done at Biosafety Level 2 under NIH Guideline III-D-4-b but the research resource facility where Defendant Kaplan was performing this research did not conform to the requirements because Biosafety Level 2 requires negative air pressure for personnel protection and the animal rooms at the facility were kept at positive air pressure at the direction of Defendant Sherwood. See attached **Exhibit J**.

89. The failure to perform research using the proper air pressure not only posed a risk to personnel but also constituted a violation of NIH Guidelines. As Defendant Kaplan's non-compliance had already led to one NIH report, Defendants chose to conceal this violation and did not report it. Instead of reporting this incident, Defendants permitted Defendant Leslie Sherwood to improperly modify the containment level of the work without IBC review. Under NIH Guideline III-D-4-b the IBC must determine the appropriate containment. See attached **Exhibit J**.

90. Beginning on or about February 2013, Cathy Price, the UL Department of Environmental Health and Safety Hazardous Waste Coordinator, was assigned review of IACUC cover sheets to determine whether or not animal research proposals required a special animal safety protocol ("SASP"). Upon information and belief Defendants were aware that Ms. Price's expertise was not in in the field

of exposures or toxicology. Upon information and belief they were also aware that Ms. Price did not have experience working in a laboratory.

91. Compounding the issue, beginning on or about November 2013, the UL IBC and/or biosafety program was experiencing a backlog of IACUC protocols for review. During this process, several animal research proposals were approved without proper safety protocols. As a result of these ongoing violations, Defendants Kaplan and Bhatnagar had modifications improperly approved by the IACUC without sending the modifications to the IBC.

Failure to Comply with NIH and CDC Select Agent Protocols Resulting in Potential Exposures and the Potential Release of Select Agents

92. Beginning on or about October 2012, the UL Institutional Animal Care and Use Committee ("IACUC") continually failed to send all animal research proposals to the UL Department of Environmental Health and Safety for review and approval. In addition, IACUC improperly allowed changes to previously approved research proposals without review and approval of the changes.

93. As a result of IACUC's failure to properly submit research proposals for review, animal research proposals for use of Select Agents were approved for use of two Select Agents at a non-Select Agent registered site located at where appropriate containment was not available.

94. By way of example, on or about 2011, Dr. Igor Lukashevich submitted a grant application for research funding for the "Development of New Bivalent Cross-Protective Arenaviral Vaccines." This project, number AI093450, was approved and Dr. Lukashevich received ongoing Government funding for this project from 2012 to at least 2014. Compliance with NIH Guidelines and CDC Select Agent Regulations was an essential part of this funding. In addition to any and all other certifications implicitly or explicitly submitted to the Government, Dr. Lukashevich submitted the Application Certification to the Government in order to receive Government Funding. In addition to the submission of the Application Certification, Dr. Lukashevich certified ongoing compliance with NIH Guidelines and CDC Select Agent Protocols via the receipt of NIH funds for this research after receipt of the related NIH Notice of Award.

95. In violation of NIH Guidelines and CDC Select Agent Protocols, as well as an agreement between the Louisville Defendants and the Louisville community to not-perform or seek authorization to perform research with Risk Group 4 Select Agents or Non-Human Primates at the Regional Biocontainment Laboratory (RBL), Dr. Lukashevich routinely pushed to work with these materials at a site where Biosafety Level 4 containment and/or appropriate non-human primate animal facilities were not available. The failure to properly submit proposals to the IBC for review throughout 2012 and 2013 resulted in a near-miss with respect to the performance of research and is one of many instances of Louisville Defendants

failing to comply with, or take seriously, NIH Guidelines and CDC Select Agent Protocols.

96. Beginning on or about October 2012 and continuing through approximately May 2013, researchers and lab workers in the RBL repeatedly failed to follow autoclave protocol, resulting in potential exposures. These potential exposures were reported as the potential release of Select Agents.

97. On or about October 2012, due to scaling up the volume of a procedure, a lab worker in the RBL used the wrong type of microvial with a snap-top lid instead of a screw-top lid with an o-ring seal. These vials were placed in a heat block located on a bench outside of the biosafety cabinet to lyse the cells to obtain the DNA. At the completion of the sterilization procedure, a tube lid popped off upon removal from the heat block and parts of the contents were spilled from the tube. A lab worker then improperly sprayed the area immediately with a disinfectant. This created an aerosol and launched samples all over the bench and the floor. This was a violation of safety protocols and was reported as a potential release of Select Agents.

98. The potential release of Select Agents poses a serious risk to public health and welfare and the failure to comply with proper safety protocols constitutes a violation of CDC Select Agent Regulations and NIH Guidelines.

99. These instances, along with others, were the subject of a whistleblower report by Plaintiff-relator Brinkley to the Federal Bureau of Investigation Weapons of Mass Destruction Liaison in Louisville in August 2014.

100. These instances, along with others, were the subject of a whistleblower report by Plaintiff-relator Brinkley to the CDC Division of Select Agents and Toxins Office as well as to the offices of Rep. John Yarmuth (D-KY), Rep. Ed Whitfield (R-KY), and Kelly Downward (R-Louisville). True and correct copies of the emails detailing these violations and other violations is attached as **Exhibit M**.

Failure to Comply with DOD Grant Requirements

101. Beginning on or about January 2012, Defendant Sherwood and others obtained funding from the DOD to train Army medics in the intubation of goats to simulate soldiers in field conditions.

102. Due to the risk of Q-Fever policy the UL Biosafety Office required a waiver for soldiers who did not get fitted for or wear a respirator during the training exercise.

103. Despite the policy, Dr. Sherwood and Vice-President for Research and Innovation, Dr. William Pierce did not adequately explain to the soldiers or to the Army the risk of exposure in conducting this training and allowed the training to be performed absent the required waivers.

104. All awards issues by the DOD are subject to the regulatory policies and procedures of the DOD Grant and Agreement Regulations (DODGARS), DOD 3210.6-R, and of the U.S. Army Medical Research and Material Command. Any non-DOD institution engaged in non-exempt research involving human subjects that is conducted or supported by the DOD must agree to the Defense Federal Acquisition Regulation Supplement (48 CFR 252.235-7004) clause that mandated compliance with 32 CFR 219 *et. seq*.

105. The failure to adequately explain the risk of harm or exposure to participants during training is generally a violation of DOD guidelines and is, specifically, a violation of the Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research standard as well as the informed consent standards of the Belmont Report referenced therein as well as the requirements of 32 CFR § 219.116 to properly explain the foreseeable risks to the subject. A true and correct copy of the November 8, 2011 DODI 3216.02 is attached as **Exhibit N.**

106. As referenced in the Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research standard, the requirements therein are contractual in nature. Moreover, all incidents of noncompliance will explicitly be responded to and investigated by the DOD. Failure to comply could jeopardize funding.

Performance of Research Under Expired IBC Protocols

107. Beginning on or about December 2013, Defendant Charles Scoggins's IBC protocol, a human gene protocol involving the application of killed pancreatic cells genetically modified to express surface receptors in order to induce an immune response in cancer patients expired and was not renewed until March 2014.

108. Despite the expiration of Dr. Scoggins's IBC protocol, patients were still treated with recombinant material. This was generally a violation of NIH Guidelines and, specifically, was a violation of NIH Guideline Section III-C-1. See attached **Exhibit J**.

109. UL administration and/or managers, including but not limited to the IBC Chair, Vice-President for Research and Innovation and/or the Director of the Department of Health and Safety, were aware of these actions and specifically decided not to report this violation within the 30 day time period required by NIH Guideline IV-B-2-b-(7), which is itself a violation of the NIH Guidelines. See attached **Exhibit J**.

110. This violation was reported to the NIH by Plaintiff-Relator Brinkley on August 1, 2014. A true and correct copy of the NIH response email is attached as **Exhibit O**.

111. This violation was eventually self-reported by Defendants on October 24, 2014. A true and correct copy of the Self-Report letter is attached as **Exhibit P**.

Performance of Research Without IBC Registration and/or Approval

112. Beginning on or about 2009 and continuing through 2014, Defendant Zhao-Hui Song, a UL professor of pharmacology, began performing research without IBC registration.

113. In addition to the un-registered performance of research, Defendant Song published work involving the use of recombinant viral vectors, human cell lines, and cannabis. That work was published in numerous scientific journals. A true and correct copy of an email with links to the specific publications is included as **Exhibit Q.**

114. UL administration and management was aware of Defendant Song's conduct, at the latest, by mid-2014 and failed to properly investigate or to timely report the matter despite Defendant Song's admission that he performed research without IBC registration.

115. Performance of research without IBC registration is generally a violation of numerous NIH Guidelines under Sections III-A to III-E and is, specifically, a violation of NIH Guideline Section IV-B-7-a-(1) and/or Section III-D-3-a.

116. This violation was eventually self-reported by Defendants on October 24, 2014. A true and correct copy of the Self-Report letter is attached as **Exhibit R**

117. Moreover, Defendant Song did not have a DEA license number for his work with cannabis and appears to have illegally piggy-backed on the license of another researcher in violation of federal law.

118. At least until mid-2014, UL does not or did not have any policy with respect to DEA licensing and has little to no oversight of those who receive them. The failure to have appropriate oversight and compliance programs is a violation of NIHGPS condition 8.3. The failure to comply with DEA requirements as well as federal law with respect to Schedule I Drugs is a violation of the NIHGPS requirement to follow all applicable laws.

119. Beginning on or about August 20, 2010, Defendant Kaplan began performing research involving bone-marrow transplants from GFP-expressing transgenic mice to wild-type mice. The research continued until approximately March 2014.

120. This research was performed absent IBC approval and in violation of NIH Guideline Section III-D-4-a. In addition to the initial violation, this violation was not reported within the 30 day time period required by NIH Guideline IV-B-2-b-(7), which is itself a violation of the NIH Guidelines. See attached **Exhibit J**.

121. This violation was eventually self-reported by Defendants on October 24, 2014. A true and correct copy of the Self-Report letter is attached as **Exhibit S**.

Failure to Have Adequate Systems to Monitor Compliance and/or Appropriately Manage Funds

122. Under NIHGPS condition 8.3, grantee organizations are expected to have systems, policies, and procedures in place by which they manage funds and activities.

123. The above-referenced systems, policies, and procedures are specifically designed to:

> [F]oster within grantee organizations and organizational culture that is committed to compliance, leading to both exemplary research and exemplary supporting systems and use of resourced to underpin that research. Actions to achieve this result should include a clear delineations of the roles and responsibilities of the organization's staff, both programmatic and administrative; written policies and procedures; training; management controls and other internal controls; performance assessment; administrative simplifications; and information sharing.

NIHGPS, Part II: Terms and Conditions of NIH Grant Awards, Page IIA-98. See attached **Exhibit D.**

124. Similarly, Section I-D of the NIH Guidelines specifically states that "institutions shall ensure that . . . research conducted at or sponsored by the institution . . . shall comply with the *NIH Guidelines*" as a condition of funding. See attached **Exhibit J.**

125. The institution receiving funding is ultimately responsible for the effectiveness of the IBC under NIH Guideline Section IV-B-2-a-(5).

126. Institutions, generally through the IBC are required to take appropriate action with respect to noncompliance under NIH Guideline Section I-D and are required to report non-compliance under Section IV-B-2-b-(7) of the NIH Guidelines.

127. It is the responsibility of the institution receiving funding to adhere to the intent of the NIH Guidelines as well as their specifics under Section IV-A of the NIH Guidelines. Thus, researching must be conducted in "full conformity" with the provisions of the NIH Guidelines under Section IV-B-1 of the NIH Guidelines. See attached **Exhibit J.**

128. In order to ensure full conformity, the institutional conducting or sponsoring the researching must "establish and implement policies" that provide for the safe

conduct of that research under Section IV-B-1-a of the NIH Guidelines. See attached **Exhibit J.**

129. Prior to and by 2010, at a minimum, the Louisville Defendants were aware of deficiencies in their policies and/or practices with respect to the NIH Guidelines for Research Involving Recombinant Molecules. Specifically, the NIH encouraged the Louisville Defendants to adopt additional systems for ensuring appropriate oversight and to engage in proper laboratory inspection procedures. See the 2010 NIH Site Inspection Letter and the 2010 UL Response attached as **Exhibits L and T**, respectively.

130. Despite receipt and acknowledgement of the 2010 NIH letter, Louisville Defendants held themselves out and continue to hold themselves out as complying with all grant requirements including all Federal, State, and local environmental health and safety regulations. By way of example, see screenshots of the University of Louisville Department of Environmental Health and Safety Website attached as **Exhibit U**.

131. Similarly, despite receipt and acknowledgement of the 2010 NIH letter, Louisville Defendants failed to implement numerous recommendations and continued to under-staff, under-fund, and under-support the IBC and related compliance units. These failures directly resulted in numerous NIH violations, including but not limited to the violations referenced herein.

132. In addition, the failure to institute the proper compliance protocols and procedures led directly to a number of near-misses and other potential violations caught just prior to the conduct of research.

133. By at least 2010 and continually worsening through the present, based in part upon the wide-ranging and numerous incidents of non-compliance referenced above as well as through numerous near-misses and/or other compliance and communications issues, Defendants were aware that they did not have in place the appropriate system, policies, and procedures in place to assure compliance

134. As a result of the Defendants' willful or reckless failure to insure a culture of compliance, individually and in cumulative effect, all research performed by Defendants beginning in at least 2010 and continuing through the present contained false certifications and statements to the United States, including but not limited to the Application Certification and related Notice of Award applicable to any and all grant applications filed by Defendants and any and all federal grant funding received by Defendants.

135. Moreover, on or about December 2014, as part of an ongoing effort to defraud the United States and cover up repeated incidents of non-compliance, Louisville Defendants reorganized its compliance process and methods in a manner that

specifically undid many of the checks and balances previously cited by the NIH as positive aspects of their compliance programs in the 2010 letter.

RETALIATORY CONDUCT FOR INTERNAL AND EXTERNAL WHISTLEBLOWING

136. Plaintiffs-relators incorporate by reference and re-allege the allegations contained in Paragraphs 1 through 135 as if fully set forth herein.

137. On numerous occasions, Plaintiffs-relators informed their supervisors and other management of Defendants that their conduct constituted noncompliance with NIH Guidelines, could affect future funding and/or grant approvals, and encouraged Defendants to alter their behavior.

138. Moreover, Plaintiffs-relators informed their supervisors and other management of Defendants that their noncompliance with NIH guidelines should be reported but Defendants chose not to do so. At this meeting numerous incidents of noncompliance were discussed and Plaintiff-relator Brinkley was specifically told she would not be retaliated against. A copy of Plaintiff-relator Brinkley's edits to the July 28, 2014 meeting notes produced by Defendants is attached as **Exhibit V**.

139. In addition to reporting the Defendants' noncompliance internally, Plaintiff-relator Brinkley sought to remedy Defendants' noncompliance by bringing it to the attention of numerous government agencies and officials including the NIH, the FBI, and multiple elected representatives. In addition to the reports previously referenced above, a true and correct copy of the email documenting Plaintiff-relator's reports to the FBI regarding Defendants' noncompliance as well as retaliation is attached as **Exhibit W.**

140. In addition to reporting the Defendants' noncompliance internally, Plaintiff-relator Whetstone sought to remedy Defendants' noncompliance by bringing it to the attention of the NIH Program for Biosecurity and Biosafety Policy (NIH/PBBP formerly NIH/OBA).

141. As a direct result of Plaintiff-relator Whetstone's attempts to encourage compliance with CDC Select Agent Regulations and/or NIH Guidelines, report noncompliance with CDC Select Agent Regulations and/or NIH Guidelines, and/or to discourage and remedy fraudulent behavior on the part of Defendants, Plaintiff-relator Whetstone was wrongfully removed from her position as Responsible Official on or about July 5, 2013.

142. As a direct result of Plaintiffs-relators' attempts to encourage compliance with CDC Select Agent Regulations and/or NIH Guidelines, report noncompliance with CDC Select Agent Regulations and/or NIH Guidelines, and/or to discourage and remedy fraudulent behavior on the part of Defendants, Plaintiffs-relators were wrongfully denied the opportunity to go to necessary and requisite training on or about September 30, 2014. Defendants were aware that this action could negatively

impact Plaintiff-relator Whetstone's Certified Biosafety Safety Professional (CBSP) credentialing.

143. As a direct result of Plaintiffs-relators' attempts to encourage compliance with CDC Select Agent Regulations and/or NIH Guidelines, report noncompliance with CDC Select Agent Regulations and/or NIH Guidelines, and/or to discourage and remedy fraudulent behavior on the part of Defendants, Plaintiffs-relators were wrongfully demoted, discriminated against, suspended, and ultimately discharged by Defendants on or about December 12, 2014. A true and correct copy of the Reduction in Force notice submitted to Plaintiffs-relators is attached as **Exhibit X**.

144. In addition to Defendants' conduct violating federal law, Defendants specifically failed to act in accordance with the University of Louisville policy regarding retaliation. A true and correct copy of the University retaliation policy is attached as **Exhibit Y**.

COUNT I

Knowingly Presenting, or Causing to Be Presented, a False or Fraudulent Claim for Payment or Approval – 31 U.S.C. §3729(a)(1)(A) and 31 U.S.C. §3730(b)

145. Plaintiff-relator incorporates by reference and re-alleges Paragraphs 1 through 144 as if fully set forth herein.

146. At all of the above-referenced times Defendants were knowingly non-compliant with the terms and conditions of the above-referenced grants and directly contradicted the Application Certification.

147. In performing all of the acts set out herein, Defendants knowingly presented, or caused to be presented, multiple false and/or fraudulent claims to the Government for its payment or approval, in violation of the False Claims Act (31 U.S.C. §3729(a)(1)(A), to the damage of the Treasury of the United States of America, and/or causing the United States to pay out millions of dollars to Defendants that it was not obligated to pay.

COUNT II

Knowingly Making, Using, or Causing to be Made or Used, a False Record or Statement Material to a False or Fraudulent Claim – 31 U.S.C. §3729(a)(1)(B) and 31 U.S.C. §3730(b)

148. Plaintiff-relator incorporates by reference and re-alleges Paragraphs 1 through 147 as if fully set forth herein.

149. At all of the above-referenced times Defendants were knowingly non-compliant with the terms and conditions of the above-referenced grants and directly contradicted the Application Certification.

150. In performing all of the acts set out herein, Defendants knowingly made, used, or caused to be made or used, false records or statements material to a false or fraudulent claim, in violation of the False Claims Act (31 U.S.C. §3729(a)(1)(B), to the damage of the Treasury of the United States of America, and/or causing the United States to pay out millions of dollars to Defendants that it was not obligated to pay.

COUNT III

Knowingly Making, Using, or Causing to be Made or Used, a False Record or Statement Material to an Obligation to Pay or Transmit Money or Property to the Government, or Knowingly Concealing or Knowingly and Improperly Avoiding or Decreasing an Obligation to Pay or Transmit Money or Property to the Government – 31 U.S.C. §3729(a)(1)(G) and 31 U.S.C. §3730(b)

151. Plaintiff-relator incorporates by reference and re-alleges Paragraphs 1 through 150 as if fully set forth herein.

152. At all of the above-referenced times Defendants were knowingly non-compliant with the terms and conditions of the above-referenced grants and directly contradicted the Application Certifications.

153. As a result of Defendants' ongoing non-compliance federal funds were used for unallowable costs and constitute a debt to the United States. Defendants' failures to report the improper diversion and/or misappropriation of funds for un-approved and unallowable usage thereby allowed Defendants to avoid and conceal their ongoing obligation to refund grant money to the issuing agency and therefore constitute reverse false claims.

154. In performing all of the acts set out herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government, or knowingly concealed and/or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the government, in violation of the False Claims Act (31 U.S.C. §3729(a)(1)(G), to the damage of the Treasury of the United States of America, and/or causing the United States to pay out millions of dollars to Defendants that it was not obligated to pay.

COUNT IV

Wrongful Discharge, Demotion, Suspension, and/or Discrimination Because of Lawful Acts Performed by the Plaintiffs in Furtherance of an Action under 31 U.S.C. §3730 and/or Other Efforts to Stop Violations of 31 U.S.C. Subchapter III — 31 U.S.C. §3730(h)

155. Plaintiffs-relators, Brinkley, and Whetstone incorporate by reference and re-allege the allegations in Paragraphs 1 through 154 as if fully set forth herein.

156. At all of the above-referenced times Defendants including by and through their agents, employees, ostensible agents, and/or representatives, were knowingly non-compliant with the terms and conditions of the above-referenced grants and directly contradicted the Application Certifications.

157. Plaintiffs-relators' actions to encourage compliance with CDC Select Agent Regulations and/or NIH Guidelines, report noncompliance with CDC Select Agent Regulations and/or NIH Guidelines, and/or to discourage and remedy fraudulent behavior on the part of Defendants were protected activities within the meaning of 31 U.S.C. §3730(h). Each Plaintiff-relator's actions were lawful acts taken by her as an employee and as an agent in furtherance of a False Claims Act action and/or constituted other efforts to stop one or more violations of the False Claims Act.

158. In performing all of the acts set out herein, Defendants including by and through their agents, employees, ostensible agents, and/or representatives, knowingly and wrongfully discharged, demoted, suspended, and/or discriminated against Plaintiffs-relators because of lawful acts performed in furtherance of an action under 31 U.S.C. §3730 and/or other efforts undertaken to stop violations of 31 U.S.C. subchapter III.

159. Brinkley and Whetstone suffered damages pursuant to 31 U.S.C. 3730(h) both as Plaintiffs-relators and in their individual capacity.

COUNT V

Retaliation Against a Public Employee for Disclosure of Violations of Law — KRS 61.102

160. Plaintiffs-relators, Brinkley, and Whetstone incorporate by reference and re-alleges Paragraphs 1 through 159 as if fully set forth herein.

161. Brinkley and Whetstone, as employees of the University of Louisville, a state entity, made or attempted to make a good faith reports regarding facts and/or information relative to actual and/or suspected violations of a law, statute, executive order, administrative regulation, mandate, rule, or ordinance of the United States, the Commonwealth of Kentucky, or any of its political subdivisions, and/or facts or information relative to actual or suspected mismanagement, waste, fraud, abuse of authority, or a substantial and specific danger to public health or safety.

162. Defendants, including by and through their agents, employees, ostensible agents, and/or representatives, subjected Brinkley and Whetstone, as employees, to acts of reprisal for making such disclosures, including but not limited to discrimination, demotion, and/or discharge.

163. Such acts violated KRS 61.102 and Brinley and Whetstone in their individual capacity are entitled to relief including but not limited to punitive damages, as set forth in KRS 61.990.

COUNT VI
Common Law Wrongful Discharge in Violation of Public Policy

164. Plaintiffs-relators, Brinkley, and Whetstone incorporate by reference and re-alleges Paragraphs 1 through 163 as if fully set forth herein.

165. There is a fundamental and well-defined public policy that the public has a general interest and a reasonable expectation that public universities by and through their agents, employees, ostensible agents, and/or representatives will comply with applicable federal and/or state laws and regulations.

166. There is a fundamental and well-defined public policy that the public has a general interest and a reasonable expectation that when employees of a public university, such as Brinkley and Whetstone, are aware of violations federal and/or state laws and regulations, the employees will report the problems to ensure compliance with federal and/or other applicable laws and regulations.

167. Brinkley and Whetstone did report violations of applicable federal and/or state laws and regulations to appropriate authoritative bodies

168. Subsequent to reporting the violations of applicable federal and/or state laws and regulations to appropriate authoritative bodies, as described in this Complaint, Brinkley and Whetstone were wrongfully terminated by Defendants, including by and through their agents, employees, ostensible agents, and/or representatives.

169. The acts and/or omissions on the part of Defendants, including those referenced in this Complaint, the acts of reporting violations by Defendants to appropriate authorities by Brinkley and Whetstone, and the subsequent discharge of Brinkley and Whetstone, constitute and give rise to a cause of action against the Defendants, under the common law, for wrongful discharge in violation of public policy

170. Brinkley and Whetstone were, in fact wrongfully discharged by Defendants including by and through their agents, employees, ostensible agents, and/or representatives, in violation of public policy for engaging in the reporting of

violations of applicable federal and/or state laws and regulations, including those referenced in this Complaint.

171. As a direct and proximate result of Defendants' wrongful discharge in violation of public policy, Brinkley and Whetstone have suffered and will continue to suffer pain, humiliation, emotional distress, lost wages, lost fringe benefits, and destruction of earning capacity.

172. Brinkley and Whetstone are entitled to relief including but not limited to punitive damages as well as general and compensatory damages in amounts to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs-relators request the following relief:

1. Judgment in favor of the United States of America against Defendants, jointly and severally, by reason of their violations of the False Claims Act as set forth above, in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than Five Thousand Dollars ($5,000), and not more than Ten Thousand Dollars ($10,000), for each violation;

2. Judgment in favor of the Plaintiff-relator, Brinkley, and Whetstone against Defendants, jointly and severally, by reason of their violations of the False Claims Act as set forth above for all compensatory and punitive damages for pain and suffering, loss of reputation, back pay, front pay, and to interest to which each Plaintiff-relator, Brinkley, and Whetstone is entitled to under 31 U.S.C. §3730(h) in their respective capacity as Plaintiffs-relators and individually, and individually pursuant to KRS 61.102, KRS 61.990, and the common law;

3. Award to each Plaintiff-relator, as a *Qui Tam* plaintiff, the maximum amount allowed pursuant to 31 U.S.C. §3730(d) of the False Claims Act based upon the United States' recovery;

4. Award to Plaintiff-relator of all reasonable expenses which the Court finds to have been necessarily incurred, including but not limited to, reasonable attorneys' fees and costs;

5. Punitive damages on all causes of action, to the extent allowable by law; and

6. Any and all other further relief to which each Plaintiff-relator, Brinkley, and Whetstone may be entitled and the Court deems proper.

Respectfully Submitted,

/s/ Vanessa B. Cantley
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DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38, Plaintiffs-relators hereby demand a trial by jury.

/s/ Vanessa B. Cantley
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EXHIBIT NOTICE

Please note all previous filed Exhibits remain unchanged from the Complaint filed on March 02, 2015, other than minor redaction and substituting number for letter references in this Complaint to match the designations on PACER, and will be served on all Defendants with this Complaint.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing has been served via the CM/ECF system on counsel of record this 28th day of December 2015.

Pursuant to FRCP 4, service will be made upon the following Defendants:

UNIVERSITY OF LOUISVILLE
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