

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF TEXAS  
GALVESTON DIVISION**

UNITED STATES OF AMERICA )  
*ex rel.* DR. CINDY BUCKMASTER )

)  
)  
) Civil Action No. \_\_\_\_\_

)  
) **FILED IN CAMERA**  
) **AND UNDER SEAL,**  
) **PURSUANT TO**  
) **31 U.S.C. § 3730(b)(2)**

Plaintiff-Relator, )

) Jury Trial Requested

v. )

BAYLOR COLLEGE OF MEDICINE )

Defendant. )

**COMPLAINT**

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This is a False Claims Act *qui tam* action by Relator to recover treble damages and civil penalties arising from the actions of Baylor College of Medicine (Baylor or BCM).

**I. STATEMENT OF THE CASE**

1. Baylor College of Medicine is an institution that has received billions of dollars in federal grants to be used for its animal research. Chief among the grantors is the National Institutes of Health (NIH), including its National Heart, Lung, and Blood Institute (NHLBI), the National Science Foundation (NSF) and the U.S. Department of Agriculture (USDA).

2. The government funds this research to advance the scientific understanding and treatment of disease and conditions such as breast and prostate cancer, heart disease, diabetes and digestive diseases, neurological disorders like epilepsy, eye diseases, newborn health and development, genetic health, allergies and asthma.

3. As the American Association for Laboratory Animal Science emphasized, the “humane and responsible care of laboratory animals is vital to **quality** research.” According to the American College of Laboratory Animal Medicine, “the appropriate use of anesthetics, tranquilizers, analgesics, and nonpharmacologic interventions in research animals is an ethical and **scientific imperative**. Pain and distress are **undesirable variables** in most scientific research projects and, if not relieved, can result in unacceptable animal welfare and **invalid scientific outcomes**.” Further notable, Baylor’s accreditor, the Association for Assessment and Accreditation of Laboratory

Animal Care International, underscores that “when research involves animals, **reliable scientific results depend on superior animal care.**” (emphasis added)

4. Under the Baylor umbrella, as a condition to its receipt of grant funds for animal research, are these statutorily mandated components with an important and trusted role in the federal-funded research:

- its Institutional Animal Care and Use Committee (IACUC)—its internal animal research oversight body to ensure compliance with federal laws and grant requirements
- its Institutional Official (IO)—the liaison between the IACUC and the government, NIH’s Office of Laboratory Animal Welfare (OLAW)
- its Principal Investigators (PIs) who oversee the labs that are supported by the federal grants and whom Baylor certifies are qualified, trained and monitored
- veterinarians who have authority and access to all research animals

5. Institutions like Baylor that receive federal grant money share responsibility for compliance and oversight to ensure good stewardship of federal funds. The relationship between the government and its grant recipients is predicated on trust.

6. Baylor answers to OLAW, the NIH entity which oversees all animal research funded by the government grants at issue in this case.

7. To receive and sustain its grant funding, Baylor has several important obligations. It must comply with all animal welfare requirements and sign an annual

**Animal Welfare Assurance** guaranteeing compliance. It also must (a) submit **annual reports** of compliance to OLAW and (b) **progress reports** directly to the grantors; and promptly report to OLAW (c) **serious** and (d) **continuing** noncompliance such as the preventable animal suffering or deaths alleged in this case.

8. However, for the last decade, Baylor's animal research program suffered from serious and continuing noncompliance in violation of animal welfare requirements. Baylor's animal research program was noncompliant when Baylor continually allowed piglets, mice, fish and other animals to suffer and die during studies involving surgical procedures and when euthanizing animals.

9. Baylor's desire to cover up its noncompliance led it to make false statements (lies) and omissions (half-truths) to the government. It routinely and knowingly avoided making required self-reports or omitted material information in its self-reports such as the fact that serious incidents were continuing in the same labs. While serious problems were pervasive, some of the labs that received the most money from the government were the worst violators of animal welfare requirements.

10. Baylor also promised the government corrective action time and again but did not follow through. This allowed pernicious problems to persist year after year. Inaction perpetuated a cycle of suffering and death of animals used in its research.

11. Baylor botched surgeries on pigs and mice, causing them unnecessary suffering and even death and allowed mice to slowly die from dehydration because of a preventable cut-off of their water supply. Yet, Baylor lied to the government about

these incidents or omitted important information about the incidents and misled OLAW to believe that it would correct the problems that led to these incidents.

12. OLAW placed Baylor on enhanced reporting at least twice—in 2013 because mice were found clinging to life in its carcass freezers—and in 2018, because of botched surgeries on mice and piglets, including unsterile procedures and not administering the necessary pre- and post-surgical pain relief. Yet, Baylor continued to thumb its nose at the regulators rather than be forthcoming about the extent and continuing nature of its violations.

13. Further, Baylor knowingly pulled the wool over OLAW’s eyes time and again, because Baylor selectively reported information about serious incidents of noncompliance so that OLAW could not connect the dots and appreciate that violations were continuing in the same government-funded labs.

14. Baylor lied and told half-truths because it feared the government would turn off the funding spigot. This kind of scheme undermines the integrity of important biomedical research funded by the government.

15. Baylor’s violations compromised the validity and reliability of the data, calling into serious question the results of research from unhealthy and unwell animals. As one OLAW official reminded Baylor, “good animal welfare is not just [ ] for the sake of the animals, it's also for the data that's generated. You can't have sick animals, dying animals and try to get good data out of that.”

16. Through its fraudulent course of conduct, Defendant knowingly submitted or caused the submission of false or fraudulent claims to the government, in violation of the False Claims Act, and the government paid those claims.

17. The amount of government funding at issue in this fraudulent scheme is significant. Since 2016 alone, Baylor has received over \$1.7 billion in funding from NIH alone and over \$200 million of that amount has funded labs for which Baylor has reported serious incidents or continuing incidents of noncompliance in these labs.

Animal Type	First Date of Reported Incident	Total Number Of NIH Reported Incidents	Total Federal Funds Received Since First Incident
Mice	3/25/2016	108	\$ 173,456,936.00
Pigs	3/27/2017	14	\$ 10,163,681.00
Primates	3/27/2017	4	\$ 3,097,720.00
Rats	10/9/2017	7	\$ 10,432,646.00
Salamanders	8/22/2017	1	\$ 6,495,775.00
<b>Total Federal Funds Received</b>			<b>\$ 203,646,758.00</b>

18. But for the Relator speaking out and blowing the whistle, Baylor will continue with business as usual until it is required to bring its animal research program into compliance with federal requirements.

19. The False Claims Act is the appropriate tool to remedy this fraudulent scheme according to the Deputy Assistant Attorney General for the United States Department of Justice: “Undoubtedly, the Department will continue to rely heavily on whistleblowers to help root out the misuse and abuse of taxpayer funds.”

20. In fact, in 2019, the Department of Justice recovered \$112.5 million from Duke University for False Claims Act violations relating to its NIH and EPA animal research grants. Said one DOJ official, “Today’s settlement demonstrates that the

Department of Justice will pursue grantees that knowingly falsify research and undermine the integrity of federal funding decisions.”

## **II. LEGAL FRAMEWORK**

### **A. The Parties**

21. Relator alleges based upon personal knowledge, relevant documents, and information, and on information and belief, the facts set forth in this Complaint.

22. Relator has extensive first-hand knowledge of Baylor’s pattern and practice alleged in this Complaint.

23. Relator was retaliated against for raising, objecting to, and opposing fraudulent conduct alleged in this Complaint.

24. But for Relator, the government would not be on notice of the allegations in this Complaint.

25. Relator has standing to bring this action pursuant to 31 U.S.C. § 3730(b)(1). Prior to becoming aware of any known public disclosure under subsection (e)(4)(a) of 31 U.S.C. § 3730, Relator voluntarily disclosed to the Government the information on which the allegations or transactions in this claim are based; and Relator has knowledge that is independent of and materially adds to any publicly disclosed allegations or transactions that may exist and have voluntarily provided the information to the Government before filing an action. Relator is either entitled to between 15 and 25 percent of the proceeds that result from this action or any settlement of the claims raised or identified herein,

under 31 U.S.C. § 3730(d)(1); or between 25 and 35 percent of the proceeds pursuant to 31 U.S.C. § 3730(d)(2).

26. Prior to filing the Complaint, and pursuant to subsection (e)(4)(a) of 31 U.S.C. § 3730, Relator voluntarily disclosed to the Government the information on which the allegations or transactions of the claims are based; and Relator has knowledge that is independent of and materially adds to any publicly disclosed allegations or transactions that may exist and has voluntarily provided the information to the Government before filing an action under this section. 31 U.S.C. § 3730(e)(4)(A). Relator is the original source of the allegations in the Complaint, as defined in 31 U.S.C. § 3730(e)(4)(B), which have not been publicly disclosed.

27. Relator has complied with all procedural requirements of the laws under which this Complaint is brought.

28. Defendant Baylor College of Medicine (Baylor) is a private nonprofit institution, located in Houston, Texas, and the organizational applicant for the grants alleged in the Complaint. Baylor partners with UTMB in Galveston on animal research sample and data analyses.

## **B. Jurisdiction and Venue**

29. This Court has subject matter jurisdiction over the claims asserted in this Complaint, pursuant to the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, and 28 U.S.C. § 1331.

30. Venue is proper in this judicial district, pursuant to 31 U.S.C. § 3732(a), because defendant may be found, resides, and/or transacts business in this District, or because an act, proscribed by 31 U.S.C. § 3729, occurred in this District.

### **C. Time Period**

31. Baylor's conduct alleged in this Complaint began at least as early as 2012 during which Baylor received over \$2.5 billion in federal funding.

### **D. The False Claims Act**

32. The False Claims Act provides, in part: Liability for Certain Acts. — (1) In general.—[ ] any person who—

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim

(C) conspires to commit a violation of subparagraph (A), (B), [ ] or

(G) knowingly makes, uses, or causes 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 conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, [ ] is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104–410 [1]),

plus 3 times the amount of damages which the Government sustains because of the act of that person. 31 U.S.C. § 3729(a)(1)(A), (B), (C), (G).

33. Under the False Claims Act, scienter must be demonstrated: Definitions— For purposes of this section— (1) the terms “knowing” and “knowingly”— (A) mean that a person, with respect to information— (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud. 31 U.S.C. § 3729(b)(1)-(2).

34. Under section (b)(2) the term “claim” — (A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that— (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government’s behalf or to advance a Government program or interest, and if the United States Government— (I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; [ ]. 31 U.S.C. § 3729(b)(1)-(2).

35. Under the False Claims Act, materiality is defined as “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” 31 U.S.C. § 3729(b)(4).

### III. REGULATORY FRAMEWORK

36. Baylor receives significant funding from numerous federal agencies for its animal research, which is at issue in this Complaint, including these:

- The National Institutes of Health (“NIH”)
- The National Science Foundation (“NSF”)
- The United States Department of Agriculture (“USDA”)

37. Using animals for research is highly regulated by the federal government, particularly when the government is funding the research, and the government is funding Baylor’s research.

#### A. Animal Welfare Requirements

38. Regulation of research animals originated in the Animal Welfare Act (“AWA”) and its implementing regulations. Pub. L. 89-544, 80 Stat.350 (Aug. 24, 1966), 7 U.S.C. § 2131 et seq; 9 C.F.R. § 1.1 et seq.

39. The AWA covers warm-blooded animals used in research, other than birds, rats, and mice that are bred for use in research. 7 U.S.C. § 2132(g). For “AWA-covered” animals, grantees like Baylor are required to provide “humane care and treatment” during their use as research animals. 7 U.S.C. § 2131(1).

40. Through the Health Research Extension Act of 1985 (“HREA”), Pub.L.99-158, 99 Stat.820 (Nov. 20, 1985), Congress supplemented the AWA with animal research protection requirements, 42 U.S.C. § 289d. HREA applies to all animals—including all Baylor research animals at issue in the Complaint—“used in biomedical and behavioral

research[,]” regardless of the species of the animal or the source of funding for research grants. 42 U.S.C. § 289d(a)(1).

41. HREA requires:

- i. the proper care of animals used in biomedical and behavioral research
- ii. animal care committees at each research entity to assure such proper care, and
- iii. that each National Institutes of Health (NIH) grant applicant include Assurances in its application that it meets these requirements and that its personnel have appropriate training available. Importantly, if the NIH determines that a research entity does not meet these legal requirements, its grants shall be suspended or revoked.

42 U.S.C. § 289d (2020).

42. The AWA, through its implementing regulations, requires similar treatment and care for AWA-covered animals, including an animal care committee to oversee this treatment and care, including for certain Baylor research animals at issue in this Complaint. 9 C.F.R. § 2.31.

43. Under HREA, all grant recipients are required to properly treat and care for animals used in research to include the appropriate use of tranquilizers, analgesics, anesthetics, paralytics, and euthanasia, and appropriate pre-surgical and post-surgical veterinary medical and nursing care for animals. Grant recipients are also required to

maintain animal care committees. 42 U.S.C § 289d (2020); see also 9 C.F.R. § 2.31(e) (AWA-covered animals).

44. The HREA required NIH to implement guidelines for the care and treatment of research animals. 42 U.S.C. § 289d(1). These requirements are embodied in the Public Health Service (“PHS”) Policy on Humane Care and Use of Laboratory Animals (“**The PHS Policy**”). The Public Health Service is a collection of eight agencies under the U.S. Department of Health and Human Services.

45. The PHS Policy incorporates the “U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training” and requires the recipient to maintain an animal care and use program based on the Guide for the Care and Use of Laboratory Animals (“**The Guide**”). The PHS Policy is intended to protect all live, vertebrate animals used or intended for use in research. The Guide requires animal research organizations to comply with the following requirements:

- “avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative.”
- “Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia.”
- “Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.”

- “Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.”
- “The living conditions of animals should be appropriate for their species and contribute to their health and comfort.”
- “Normally, the housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.”
- “Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals.”
- “Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.”

46. The NIH Grants Policy Statement identifies the requirements that serve as the terms and conditions of NIH grant awards. By accepting an award, grantees “must demonstrate compliance ...with a number of public policy requirements[,] [t]he more significant of [which . . . includes] research involving live vertebrate animals.” 42 U.S.C. § 289d

47. Grant recipients must also comply with the PHS Policy and have “an approved Animal Welfare Assurance ...on file with the Office of Laboratory Animal Welfare (OLAW) at the time of award” and such organizations “bear ultimate

responsibility for compliance with the PHS Policy in all PHS supported activity.” 42 U.S.C. § 289d

48. In addition to funding animal research grants, NIH regulates all public health service activities concerning the treatment of animals used in research studies, including for its NHLBI and other agencies like the NSF, under its Office of Laboratory Animal Welfare (“OLAW”). OLAW is the office within the NIH that (a) implements animal welfare policy requirements for NIH animal research grants (and other agency animal research grants, including its NHLBI, and the NSF) such as the Baylor research grants at issue in this Complaint and (b) monitors organizations like Baylor’s compliance with the PHS Policy for all laboratory animal welfare activities. 42 U.S.C. § 289d

49. All grantor agencies, including NIH, its NHLBI, the NSF and the USDA—the grantors at issue in this case—require grant recipients like Baylor to comply with the AWA and implementing regulations. Baylor is also required to comply with the Guide for the Care and Use of Laboratory Animals and the Public Health Service Policy and to execute Assurances that include promises to comply with such requirements as a funding requirement for NIH/NHLBI and NSF grants.

### **B. Baylor’s Obligations**

50. Institutions like Baylor that receive federal grant money share responsibility for compliance and oversight to ensure good stewardship of federal funds. The relationship between the government and its grant recipients is predicated on trust.

51. An Animal Welfare Assurance (“**Assurance**”) is the document submitted by grant recipients like Baylor assuring institutional compliance with the PHS Policy. By executing the Assurance, Baylor certifies that it:

- “will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals”
- “is guided by the ‘U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training’”
- “acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance....[] will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, as well as all other applicable laws and regulations pertaining to animal care and use”
- “has established and will maintain a program for activities involving animals according to the Guide for the Care and Use of Laboratory Animals” (Guide)”

52. An Assurance must be on file with OLAW at the time of award for all recipient organizations receiving PHS support for research or related activities using live vertebrate animals. Grant recipients like Baylor must establish appropriate policies and

procedures to ensure the humane care and use of animals and bear ultimate responsibility for compliance with the PHS Policy in all PHS supported activities. 42 U.S.C. § 289d(c)

53. Institutions like Baylor must provide certain guarantees in their Assurances under the HREA.

54. First, the Assurance must describe the institution's program for the care and use of animals in PHS-conducted or supported activities, in accordance with AWA and HREA requirements to include certification that it has an institutional program for animal care and use, including:

- An Institutional Official (IO)
- An Institutional Animal Care and Use Committee (IACUC)
- A Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has program authority and responsibility for activities involving animals at the institution

42 U.S.C. § 289d(c)

55. Second, each institution must assure either that its program and facilities are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC), or that they are evaluated by their internal IACUC (described below). Baylor's Assurance promised that it was accredited by AAALAC. 42 U.S.C. § 289d(c)

56. The AAALAC International accreditation program is comprised of animal research experts. It evaluates organizations that use animals in research, teaching or

testing and accredits those that meet its standards for animal research and treatment. As part of the accreditation process, AAALAC evaluators conduct a comprehensive on-site assessment. The site visitors' report is then reviewed by the entire Council on Accreditation and accreditation status is determined. If deficiencies are found, they are outlined in a letter and the institution is given a period of time to correct them. Once the deficiencies are corrected, accreditation is awarded. To maintain accreditation, subsequent site visits and in-depth re-evaluations are held every three years.

57. Baylor has promised in its Assurance that it is accredited by AAALAC. Further, federal regulations require institutions like Baylor to report on whether AAALAC has evaluated and accredited it for research involving animals. The individuals who conduct these evaluations are highly regarded experts in animal care and research, including professors, researchers, and veterinarians.

58. AAALAC may defer accreditation of an institution if there are issues that need to be addressed by the institution. Deferred accreditation is where the institution is accredited but must correct the mandatory items and submit written response actions that addressed all the mandatory issues within the time specified by AAALAC; failure to fully correct the mandatory issues of deferred accreditation will result in probation and may result in the revocation of accreditation. 42 U.S.C. § 289d(c)

59. Third, each organization, including Baylor, that conducts animal research with federal grant money is required to establish an **Institutional Animal Care and Use Committee** (“IACUC”). Baylor has an IACUC, as alleged in this Complaint. 42 U.S.C. § 289d; 9 CFR § 2.31.

60. The Institution's Assurance must include the names, position titles, and credentials of the IACUC chairperson and the members. 42 U.S.C. § 289d; 9 CFR § 2.31

61. Each IACUC must include at least these members: a veterinarian, a practicing scientist experienced in animal research, a person whose primary concerns are in a nonscientific area, and a person who is unaffiliated with the institution. Federal animal welfare requirements do not allow the IACUC to designate its duties to other individuals, such as an administrative arm. 42 U.S.C. § 289d; 9 CFR § 2.31

62. The IACUC is required to oversee and evaluate the institution's animal research program to ensure compliance with federal requirements to include:

- Evaluate the institution's program for humane care and use of animals at least once every six months for compliance with federal regulations, and submitting reports of these evaluations, including descriptions of noncompliance with federal regulations, to the Institutional Official (the IO), the liaison between the IACUC and OLAW
- Review and investigate concerns involving the treatment of research animals at the institution
- Review and approve (or withhold approval from) proposed research involving live animals based on, as relevant here, whether the proposed research complies with federal regulations regarding animal care and treatment

- Ensure that individuals who perform research on animals are properly trained
- Post-approval monitoring (PAM), the ongoing monitoring of (a) approved research to ensure continued compliance with federal regulations, and (b) labs and researchers within the institution who have previously failed to comply with federal regulations to ensure that the noncompliance does not continue

42 U.S.C. § 289d; 9 CFR § 2.31

63. The IACUC, through the Institutional Official, is required to make **two types of reports** to OLAW, as a condition of continued funding for animal research activities:

- An **annual report** confirming compliance with animal welfare requirements, including compliance with its **Assurances**
- A promptly filed **report of any (a) serious or (b) continuing noncompliance** with the PHS Policy, and any serious deviations from the Guide for the Care and Use of Laboratory Animals. Serious noncompliance includes noncompliance that poses a risk of harm to animals and failure to adhere to approved research protocols.

42 U.S.C. § 289d; see also 9 C.F.R. § 2.31(c)(3) (requiring institutions conducting research on AWA-covered animals to report to the USDA significant deficiencies that do or may pose “a threat to the health or safety of the animals” that have not been corrected).

64. Institutions like Baylor are also required to submit **progress reports** of compliance directly to each of its government grantors.

65. NIH shall “suspend or revoke” grants if animal care and treatment fail to meet legal requirements and the organization does not correct the noncompliance. Grant awards will not be disbursed during times when the grant recipient fails to comply with award terms, conditions and Assurances. 42 U.S.C. § 289d

66. Grant Recipients are expected to properly administer government-funded research activities and comply with applicable regulations and policies. The **Principal Investigator (PI)** is the lead scientist at the institution on a research project and is responsible for conducting an animal study in compliance with federal regulations, with oversight by the funded-organization’s IACUC.

67. Principal investigators and their organizations are accountable for the protection of the research animals in their care from the earliest stages of planning until a study is completed, including:

- Describing proposed use of animals in grant applications
- Ensuring research is conducted according to the protocol
- Complying with institutional policies and procedures

68. Applications for federal grant funding must include a concise description of the proposed procedures to be used that involve vertebrate animals, a justification for the appropriateness of the animals chosen, description of interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort,

distress, pain and injury. Grant recipients must also attest that the euthanasia method to be used is consistent with the American Veterinary Medical Association Guidelines.

69. The IACUC must also approve **animal research protocols** before principal investigators receive federal funding. The IACUC may only approve proposed protocols that comply with federal requirements, including those requiring researchers to minimize pain and distress, provide appropriate animal living conditions and veterinary care, give the names and qualifications of personnel who will perform research on animals, and describe an approved method of euthanasia and endpoint criteria (the point at which an animal is suffering and therefore must be euthanized). The use of animals as described in the protocol approved by the IACUC must be congruent with the description in a grant application. 9 CFR § 2.31

70. In summary, the regulatory framework outlined in this Complaint is applicable to Baylor and the allegations in the Complaint.

#### **IV. THE FRAUD SCHEME**

71. For at least a decade, Baylor's animal research program suffered from serious programmatic problems that led to false statements and omissions made in government funding requests and to government regulators in their oversight of Baylor's program.

72. Worse, the government (OLAW) notified Baylor of its serious deficiencies and regulatory noncompliance, even placing Baylor on an "enhanced reporting" schedule

twice. Yet, Baylor continued to commit violations, make false statements and material omissions, and cover up its ongoing noncompliance.

73. Baylor knew that it was required to promptly self-report serious incidents of noncompliance. Federal regulations require that self-reports be “prompt,” even if only preliminary until further investigation. 42 U.S.C. § 289d; 9 CFR § 2.31

74. Further, OLAW explicitly told Baylor that it should include dates of serious incidents of noncompliance and make preliminary reports, appreciating that a final report would take more time.

75. However, Baylor’s animal research program did not adhere to government requirements in at least the following ways:

- in violation of federal requirements, (a) Baylor failed to provide the proper care and treatment of animals used in its research, including during pre- and post-surgical procedures and surgeries, and when euthanizing animals, and (b) made repeated false statements to the government to conceal its improper care and treatment of animals in violation of federal requirements
- in violation of federal requirements, Baylor routinely and knowingly (a) did not report material information to the government as part of its self-reports (half-truths), (b) did not make self-reports at all, or (c) did not promptly self-report

- Baylor did not correct its persistent problems to avoid future violations of federal requirements; thereby perpetuating its cycle of knowingly causing harm, pain and death to research animals under its care
- Baylor knowingly misled the government to believe that it was taking corrective actions to prevent future violations of federal requirements when, in fact, it was not doing so

76. Baylor's research program is comprised of hundreds of labs, each required to be overseen by a principal investigator (PI) responsible for all research on a particular government-funded grant, including at least these agencies that funded Baylor research: NIH/NHLBI, the NSF and USDA.

77. While the serious problems alleged in this Complaint were pervasive throughout Baylor's animal research program, the labs responsible for the largest dollar government research grants were the most common violators of federal animal welfare requirements.

78. Hundreds of millions of dollars in NIH and other agency grant funding were jeopardized because Baylor's research was compromised by the types of serious incidents alleged in this Complaint, as shown by these examples:

- \$173.4 million in government funding was jeopardized by serious incidents involving mice
- \$10 million in government funding was jeopardized by serious incidents involving 14 piglets

- \$6.4 million in government funding was jeopardized by one serious incident involving a salamander
- \$10.4 million in government funds was jeopardized by serious incidents involving seven rats
- \$3 million in government funding was jeopardized by serious incidents involving 4 primates

Animal Type	First Date of Reported Incident	Total Number Of NIH Reported Incidents	Total Federal Funds Received Since First Incident
Mice	3/25/2016	108	\$ 173,456,936.00
Pigs	3/27/2017	14	\$ 10,163,681.00
Primates	3/27/2017	4	\$ 3,097,720.00
Rats	10/9/2017	7	\$ 10,432,646.00
Salamanders	8/22/2017	1	\$ 6,495,775.00
Total Federal Funds Received			\$ 203,646,758.00

79. To avoid having the government turn the funding spigot off, Baylor paid lip service to corrective action plans and mitigation of serious incidents of noncompliance in the labs responsible for government-funded research—calling into question the validity and reliability of research results that came out of those labs.

80. As described in this Complaint, Baylor repeatedly told OLAW and government grantors (e.g., NIH/NHLBI, USDA, the NSF) that it was complying with federal laws and regulations related to animal welfare when it knew that it was not. Its representations in its Assurances and annual reports to OLAW were false, as well as its representations in its progress reports submitted to the federal agencies, which provided Baylor the grants.

81. Baylor also knowingly did not report material violations in its mandatory reports of noncompliance to OLAW because it knew that such reporting would highlight

that these violations may have compromised the validity and reliability of the government-funded research.

82. Baylor knowingly chose to not report or correct violations of government requirements that were material to the receipt of federal grants because Baylor did not want to have the government-funding spigot paused or turned off.

83. Baylor's violations of animal welfare requirements during biomedical research threatened the integrity of research funded by taxpayer dollars.

84. Through its fraudulent course of conduct, Defendant knowingly submitted or caused the submission of false or fraudulent claims to the government, in violation of the False Claims Act, and the government paid those claims.

#### **A. Whitewashing Animal Suffering and Deaths**

85. Baylor was required to report all serious **and** continuing noncompliance to OLAW, including preventable animal harm, pain and deaths that occurred during studies that involved surgical procedures on animals. In fact, Baylor was required to certify and did certify in its Assurances to OLAW that it would report such noncompliance.

86. Baylor knew that compliance with federal animal welfare requirements was material to its continuing receipt of grant funding for animal research and OLAW and other government grantors repeatedly reminded Baylor of its Assurances of compliance with these requirements.

87. As the OLAW Deputy Director reminded Baylor in 2019:

In order for Baylor to receive money to do animal research from NIH or the National Science Foundation, an assurance

must be in place, which is a contract. But that contract has to be met at your end too, because if it's not, **we have to make sure that this federal money is being spent to conduct the research in a humane fashion.**

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**Having one case after another of animals reviving, after being attempted to euthanized, that is a serious animal welfare concern.** And we are there to assure the public [and] Congress, that our grantees are doing things in a humane fashion. And when the same institution puts in the exact same report with these very serious animal concerns, that really concerns us too. And after a while, **if Congress hears enough of this and enough requests to stop funding for this institution because they don't know what they're doing, they may want us to take action.** It's never gotten to that, because most institutions know the consequences of revoking assurance, **but some of these avoidable problems really are serious, serious animal concerns that the public understands and the public is the one that's funding this work.**

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**But good animal welfare is not just also for the sake of the animals, it's also for the data that's generated. You can't have sick animals, dying animals and try to get good data out of that. I'm trying to emphasize that the public is funding this work. They want to be assured that the work's being done humanely. The point of reporting non-compliance to us is not so that we punish you, it's so that we know, yes, this bad thing has happened and here's how we fixed it.** And once we know that we say, fine, we're going to move on, **but having the same thing happen again and again, that's when we start escalating sanctions too.**

(emphasis added)

88. However, preventable animal suffering and deaths did occur during studies involving surgical procedures with animals and Baylor knowingly chose to not report those deaths to OLAW to avoid the disclosure of widespread harm, pain and animal deaths and the withdrawal of government funding.

89. To make it appear that Baylor was meeting its reporting obligations, it instead reported technical infractions or made partial disclosures of the incidents (half-truths), thereby whitewashing serious harm and deaths, which it knew would compromise the integrity of the research and its funding spigot. However, the actual harm or pain caused to animals was knowingly omitted from the descriptions of the incidents. Baylor believed that partial disclosures (half-truths) would give it the appearance of being forthcoming and prevent government funding from being halted or withdrawn.

90. Baylor also failed to report that many of the incidents were not only **serious**, but also **continuing**, thus knowingly failing to comply with this separate regulatory requirement.

91. The knowing concealment of serious incidents from OLAW violated federal requirements and ensured Baylor a steady flow of government funding just as Baylor intended.

92. Through its fraudulent course of conduct, Defendant knowingly submitted or caused the submission of false or fraudulent claims to the government, in violation of the False Claims Act, and the government paid those claims.

## **1. Botched Euthanasia of Mice**

93. Baylor knowingly failed to put in place a system to ensure compliance with government requirements that were material to the receipt of federal grants. Because of these failures, animal euthanasia procedures were not properly performed, and mice suffered in connection with government-funded studies, thereby calling into question the integrity of the research.

94. At least as early as September 2012, Baylor knew that it was not properly euthanizing animals. Animals are required to be painlessly killed. However, Baylor researchers were putting mice to sleep and discarding them into carcass freezers, where many were found later, alive and crawling among the dead.

95. Clinging to life in a freezer would be terrorizing and cause suffering to a mouse. For these reasons, federal regulations require that institutions like Baylor use euthanasia methods that:

- “induce loss of consciousness and death with no or only momentary pain, distress, or anxiety”
- are “predictable and controllable,” and
- are “performed by personnel skilled in methods for the species in question” who also confirm the death or engage in a “secondary method of euthanasia” to “ensure death.”

(“Euthanasia means the humane destruction of an animal accomplished by a method that produces rapid unconsciousness and subsequent death without evidence of pain or

distress, or a method that utilizes anesthesia produced by an agent that causes painless loss of consciousness and subsequent death.”) 9 C.F.R. § 1.1

96. Baylor knew its euthanasia methods were noncompliant because they also violated their written compliance policies, which required researchers to observe animals to confirm that the animal was not breathing and the heart not beating; and, for infant animals, to use a secondary method of euthanasia to ensure death.

97. Yet, in one month alone (December 2012), 57 mice were discovered alive in the freezer following euthanasia by Baylor researchers. Another 158 infant mice were not euthanized through a secondary method, in violation of federal requirements, including research protocol requirements, which meant that they too may have been alive for some time while in the freezer.

98. Even though Baylor’s knowledge dated back to at least September 2012, Baylor did not report these troubling findings to OLAW until January 2013. Further, Baylor limited what it did report, leaving out material information, including: (1) that euthanized mice had been found alive in the freezer at least as early as September 2012, and (2) that dozens and possibly hundreds of mice, including mouse pups, had been harmed in this way.

99. Based on even the limited information shared by Baylor for each mouse incident, OLAW required Baylor to explain: (1) why it occurred, (2) why it had not been reported, and (3) what corrective actions had been taken; thereby demonstrating that these violations were serious and material to the government.

100. Astoundingly, Baylor researchers continued to improperly euthanize animals. Below is an example of a report of animals found alive in freezers from January 23, 2013, to April 2, 2013 (“LMP” stands for “live mouse pup,” i.e., infant mouse found alive after euthanasia, and “LAM” stands for “live adult mouse, i.e., adult mouse found alive after euthanasia):

Date	Location	ID	Name	Protocol	PI	Finding
1/23/13	NRI	[REDACTED]	[REDACTED]	AN-5596	[REDACTED]	11 LMP
1/31/13	TMF	[REDACTED]	[REDACTED]	AN-5858	[REDACTED]	5LAM & 9LMP
2/5/13	TMF	[REDACTED]	[REDACTED]	AN-2234	[REDACTED]	1 LMP
1/23/13	NRI	[REDACTED]	[REDACTED]	AN-3327	[REDACTED]	10 LMP
2/11/13	TCH	[REDACTED]	[REDACTED]	AN-2126	[REDACTED]	6 LMP
2/20/13	TMF	[REDACTED]	[REDACTED]	AN-1506	[REDACTED]	9 LMP
2/22/13	TMF	[REDACTED]	[REDACTED]	AN-2212	[REDACTED]	3 LMP
2/25/13	TMF	[REDACTED]	[REDACTED]	AN-1506	[REDACTED]	1 LAM
3/13/13	TMF	[REDACTED]	[REDACTED]	AN-3142	[REDACTED]	3 LMP
3/19/13	TMF	[REDACTED]	[REDACTED]	AN-2523	[REDACTED]	1 LAM
3/26/13	TMF	[REDACTED]	[REDACTED]	AN-5713	[REDACTED]	1 LMP
4/2/13	TMF	[REDACTED]	[REDACTED]	AN-4195	[REDACTED]	1 LMP

101. On information and belief, these numbers above are underreported.

102. For example, on February 18, 2013, a Baylor researcher deliberately placed 9 mouse pups in a freezer outside the designated animal research area to avoid the discovery of improperly euthanized mice.

103. The same researcher also wrote a fake Baylor identification number on the bag containing the pups, knowing the lab had not followed proper euthanasia procedures.

104. Upon information and belief, Baylor did not report these troubling incidents to OLAW.

105. Baylor knew that researchers routinely did not properly euthanize mice and used fake identification numbers to avoid detection. However, the practices were not stopped, and mice continued to be improperly euthanized and suffered because of it.

106. Instead of meeting its obligations to report the botched euthanasia of mice, Baylor whitewashed these incidents as if they were harmless. These omissions misled OLAW about the extent of Baylor's noncompliance with federal requirements, including that the incidents involved **continuing** noncompliance.

107. Even given the limited information that Baylor reported, OLAW placed Baylor on "enhanced reporting" to monitor Baylor's compliance with federal euthanasia requirements.

108. Had Baylor truthfully reported to the government, a further investigation may have been conducted or directed to determine whether the research data resulting from federally funded studies involving these animals were valid and reliable, and whether grant funding should be suspended or revoked based on the serious and continuing noncompliance.

109. Even after being placed on "enhanced reporting," Baylor continued to allow serious and continuing noncompliance in its labs.

110. Through its fraudulent course of conduct, Defendant knowingly submitted or caused the submission of false or fraudulent claims to the government, in violation of the False Claims Act, and the government paid those claims.

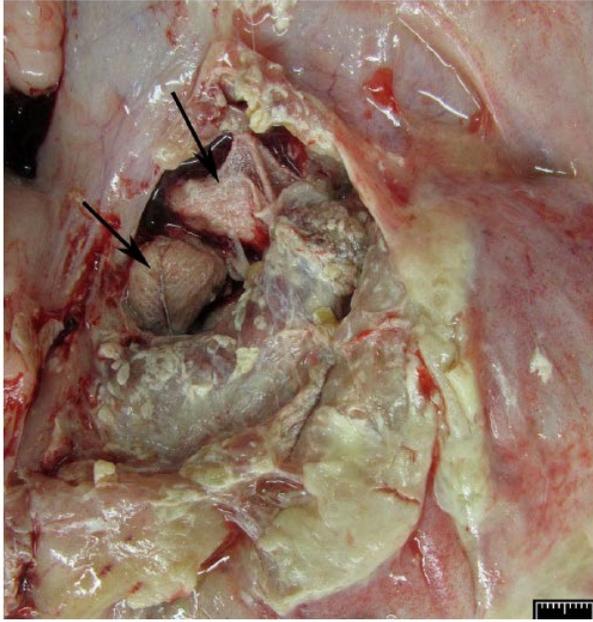
## **2. Botched Surgeries on Pigs and Piglets**

111. Baylor allowed pigs and piglets in government-funded studies to unnecessarily suffer and die, but chose to not prevent recurrences, and misled OLAW and other government agencies about its corrective actions.

112. On December 12, 2016, surgery was performed on a pig in the lab headed by “PI-A.” After the surgery, a report written by Baylor’s IACUC noted that the pig was “acutely declining,” “became progressively worse” and had to be euthanized because of the “pain/discomfort,” which did not improve.

113. The necropsy (or autopsy) report on the pig showed that:

- As shown by the photo below, the surgeon left “a wad of gauze sponges” inside the pig, and that the pig’s pain and distress was consistent with “irritation from . . . [the] bundle of 2 large gauze sponges left in the surgical site”
- the surgical technique “may or may not have also contributed” to the pig’s pain and decline



Black arrows indicate a wad of gauze sponges lodged in the area of surgical dissection.

114. However, in its report to OLAW, Baylor falsely:

- stated that “the cause of death was unrelated to the retained sponges” even though the necropsy report showed that the pig’s “inflammation and necrosis...[wa]s consistent with ‘irritation resulting from’” the gauze pad bundle
- omitted that post-surgery, the pig had “begun acutely declining and became progressively worse despite treatment with intravenous antibiotics and fluid resuscitation”
- omitted that Baylor had to euthanize the pig, leaving the reader of the self-report to conclude that the pig’s death occurred naturally
- omitted that the pig had endured pain and distress, leading to the euthanasia

115. These reported lies and half-truths were in “serious noncompliance with federal requirements” because they violated PHS Policy to ensure that “[p]rocedures with animals will avoid or minimize discomfort, distress, and pain to the animal’s consistent with sound research design.”

116. As shown below, Baylor also reported lies and half-truths involving serious incidents that occurred at another lab involving piglets headed by principal investigator “PI-B”, including:

- knowingly not reporting serious noncompliance in a timely fashion
- knowingly not mitigating serious incidents in violation of animal welfare requirements
- knowingly making false representations to OLAW about these incidents

117. Baylor reported to OLAW four more serious incidents involving piglets in one government-funded (NIH and USDA) study in “PI-B’s” lab that occurred over 15 months. Three of the four incidents involved piglet suffering and deaths.

118. For each of these serious incidents, Baylor falsely represented to OLAW that it took corrective action to ensure that staff were qualified and well-trained. In fact, serious incidents involving botched surgeries and procedures continued in the same lab headed by “PI-B”. However, Baylor’s self-reports were knowingly misleading and omitted material information, including the fact that the serious incidents occurred in the same lab. Therefore, OLAW did not have the information it needed to connect the dots

and impose “escalating sanctions” as warned by the OLAW Deputy Director, or to withdraw funding.

119. On March 27, 2017, Baylor reported (the first of four serious incidents involving piglets in the lab headed by “PI-B”):

- one piglet that should have been euthanized died on its own after unnecessary suffering for 1 ½ hours because the researcher was not qualified to monitor the piglet or euthanize it.
- it would take corrective actions to include training staff on humane endpoints, euthanasia, and the need to notify the on-call veterinarian of the death of an animal on weekends or holidays.

120. Baylor failed to report to OLAW that the incident had occurred nine months earlier, in June 2016.

121. Serious incidents involving piglets continued unabated even though Baylor promised it had provided the proper training.

122. Two days later, on March 29, 2017, Baylor reported (the second of four serious incidents involving piglets in the lab of “PI-B”) that surgeries were conducted improperly in “PI-B’s” lab on 8 piglets, and one piglet died. The report noted that the surgeries constituted “serious noncompliance” with federal requirements because researchers:

- administered anesthesia for longer than allowed in the approved protocol
- did not properly close surgical sutures

- did not hydrate the eyes of the piglets during surgery
- did not properly sterilize for surgery
- used an anesthesia machine that was not appropriate for the piglets because of their small size and used the machine improperly
- allowed an unqualified researcher to participate in the surgery

123. Once again, Baylor misled OLAW by claiming that corrective actions to include retraining researchers on proper surgical care was taken.

124. Materially, Baylor omitted from its report that:

- this was the second piglet death in the same lab using the same faulty protocols
- this incident represented not only **serious** noncompliance but also **continuing** noncompliance with federal requirements
- Baylor had already claimed that corrective actions had been taken to include retraining researchers in this lab (including “PI-B”) on proper surgical care

125. In response to this serious incident, OLAW ordered Baylor to make “prompt preliminary” reports “of noncompliance issues,” followed by a “final report once corrective action has been taken” and to include the dates of incidents in the future.

126. Three months later, on June 29, 2017, the Chair of the IACUC informed “PI-B” that because of “continuing concerns related to surgeries” in the lab, a

veterinarian would “be included as a member of the surgery team” for all surgeries conducted under the research protocol.

127. However, Baylor never reported to OLAW that this oversight was necessary or that noncompliance in the lab was continuing, thus necessitating this oversight.

128. On September 25, 2017, despite the required mitigation, the USDA discovered during a routine inspection that another piglet died only three days postpartum in the lab of “PI-B.”

129. The USDA’s inspection report on the incident cited Baylor because it did not “ensure that all personnel involved in animal care and use are appropriately qualified and trained” and ordered Baylor to demonstrate that it was compliant with acceptable standards for animal treatment.

130. On October 25, 2017, Baylor wrote to the USDA promising: (a) that a training plan had been developed that was approved by the IACUC, and that staff would be trained by November 8, 2017; and (b) the (unnamed) PI overseeing the lab would be required to “look at all animals and sign off on their records on a daily basis during studies” and meet with the veterinarian on a weekly basis to ensure that any problems would be timely corrected.

131. Baylor did not report to OLAW this preventable piglet death that occurred in September 2017 until January 19, 2018. When it did, it omitted material information from the report (half-truths), including that:

- the incident involved the same lab again
- the noncompliance was not only **serious** but also **continuing** and was the third report of noncompliance from this lab
- the previous training, if it occurred at all, was completely ineffective because it had not prevented a further preventable piglet suffering and death
- USDA issued an inspection report and ordered Baylor to become compliant

132. Baylor fraudulently led OLAW to believe that it corrected the problems; as shown by the continued noncompliance, corrective action was not implemented to prevent recurrence. Further, Baylor had earlier reported to OLAW that similar corrective action had been taken but omitted in this report that the earlier corrective action had failed to prevent continuing noncompliance.

133. Indeed, serious incidents involving piglets in this same lab continued unabated.

134. On June 25, 2018, Baylor reported (the fourth serious incident involving piglets in the lab headed by “PI-B”) these failures in surgical procedures:

- surgery was improperly performed without a sterile field
- the same surgical pack and suture materials were improperly used for all three piglet surgeries
- no one monitored the body temperatures of the piglets at appropriate intervals during surgery, as required.

135. Notably, Baylor falsely reported to OLAW that all animals affected by the noncompliance “recovered from surgery with no complication.”

136. Baylor omitted the following material information in the report to OLAW (half-truths):

- the dates that these failures took place
- the failures occurred in the lab that was a repeat violator, i.e., “PI-B’s” lab
- the failures involved the same protocols on the same government-funded project as the previous three reports
- a piglet suffered and died because a catheter had been inserted in the wrong place in the piglet’s body, which blocked blood flow to the piglet’s brain

137. Improper surgical procedures caused this piglet’s death just like improper surgical procedures had caused piglet deaths as far back as the March 2017 report, over 15 months earlier.

138. Baylor fraudulently led OLAW to believe that it corrected the problems; as shown by the continued noncompliance, corrective action was not implemented to prevent recurrence. Further, Baylor had earlier reported to OLAW that similar corrective action had been taken but omitted in this report that the earlier corrective action had failed to prevent continuing noncompliance:

- “[a] member of the [Baylor]-CCM [Baylor Center for Comparative Medicine] Veterinary staff must continue to attend all surgical procedures”

- it required training on health records documentation, monitoring, and reporting for all staff.

139. Astonishingly, on July 16, 2018, a Baylor veterinarian reported to his supervisor that “PI-B” was not “personally checking animals,” had not attended any meetings with the veterinarians, and had “never participated” in the USDA corrective action plan.

140. Therefore, Baylor lied to the government agencies because it never took steps to ensure that it implemented or monitored the corrective action plan and did not report these failures to the USDA and OLAW.

141. Had Baylor truthfully reported to the government, a further investigation may have been conducted or directed to determine whether the research data resulting from federally funded studies involving these animals were valid and reliable, and whether grant funding should be suspended or revoked based on the serious and continuing noncompliance.

142. Baylor knowingly concealed from OLAW that these botched procedures on piglets involved the same lab (“PI-B’s” lab) as the prior incidents and were not isolated incidents; and that past corrective action was not taken as promised.

143. Instead of meeting its obligations to report serious incidents, including animal suffering and deaths, Baylor whitewashed these incidents as harmless. These omissions misled OLAW to believe that Baylor was compliant with federal requirements.

Further, Baylor did not take correction action and allowed these serious problems to continue.

144. Had Baylor truthfully reported to the government, a further investigation may have been conducted or directed to determine whether the research data resulting from federally funded studies involving these animals were valid and reliable, and whether grant funding should be suspended or revoked based on the serious and continuing noncompliance.

145. In summary, the reports and (material) half-truths made to OLAW include these continuing and unabated serious incidents in “PI-B’s” lab, all of which were incidents of serious noncompliance of federal requirements:

DATE SERIOUS INCIDENT OCCURRED	DATE SERIOUS INCIDENT REPORTED TO OLAW	DESCRIPTION OF SERIOUS INCIDENT	CORRECTIVE ACTION REPORTED TO OLAW	OMISSIONS (HALF-TRUTHS) & LIES TO OLAW
6/26/2016	9 months later, on 3/27/2017	Botched & delayed euthanasia of piglet	Promised to provide training to PI-Bs lab	
4/1/2016	12 months later, on 3/29/2017	8 botched piglet surgeries, leading to 1 death	Again promised to provide training	this lab ("PI-B") was a repeat violator; reporting was delayed; not only serious but also <b>continuing</b> noncompliance
9/25/2017	4 months later, on 1/19/2018	Preventable piglet death, 3 days postpartum	Again promised to provide training	this lab ("PI-B") was a repeat violator; reporting was delayed; USDA cited Baylor for the incident; not only serious but also <b>continuing</b> noncompliance
5/18/2017 and 6/13/2017	13 months later, on 6/25/2018	More botched piglet surgeries	Again promised to provide training	this lab ("PI-B") was a repeat violator; reporting was delayed; falsely reported that all animals "recovered... with no complication" when one piglet actually suffered and died

146. Baylor falsely led OLAW to believe that it corrected its problems; however, as shown by the continued noncompliance, corrective action was not implemented to prevent recurrence. On information and belief, these numerous violations impacted the validity and reliability of the government-funded research.

147. Through its fraudulent course of conduct, Defendant knowingly submitted or caused the submission of false or fraudulent claims to the government, in violation of the False Claims Act, and the government paid those claims.

### **3. Preventable Dehydration of Mice**

148. Baylor allowed mice to suffer and die from dehydration in connection with a government-funded study but chose to not report these deaths to OLAW.

149. On September 18, 2019, the government-funded lab run by principal investigator “PI-C” emailed the chair of the IACUC to inform him that several mice had died from dehydration because the water supply to a rack of mouse cages was disconnected, and noted this “significantly affects our breeding, our research, and our work.” Because of this preventable cut-off of their water supply:

- another mouse was euthanized because it appeared gaunt and moved in a way that suggested it was in pain, having suffered from the effects of dehydration.
- other mice were small in appearance and appeared also to be in pain.

150. Yet, on January 13, 2020, Baylor lied to OLAW, reporting that despite depriving the animals of their water supply, they “appeared healthy with no clinical symptoms of dehydration.” This was an outright lie to OLAW.

151. Instead of meeting its obligations to report the deaths of mice, Baylor whitewashed the incident as a harmless one. These omissions misled OLAW to believe that Baylor was compliant with federal requirements.

152. Had Baylor truthfully reported to the government, a further investigation may have been conducted or directed to determine whether the research data resulting from federally funded studies involving these animals were valid and reliable, and whether grant funding should be suspended or revoked based on the serious and continuing noncompliance.

153. Through its fraudulent course of conduct, Defendant knowingly submitted or caused the submission of false or fraudulent claims to the government, in violation of the False Claims Act, and the government paid those claims.

#### **4. Botched Surgeries on Mice**

154. Baylor allowed mice to suffer and die from harmful surgical practices in connection with government-funded studies but chose to not report these deaths to OLAW.

155. On August 29, 2019, four mice involved in surgeries in the lab headed by “PI-D” were not administered the necessary postoperative analgesics in violation of federal requirements, including research protocol requirements. One mouse was found dead after the surgery (as shown in the photo below):



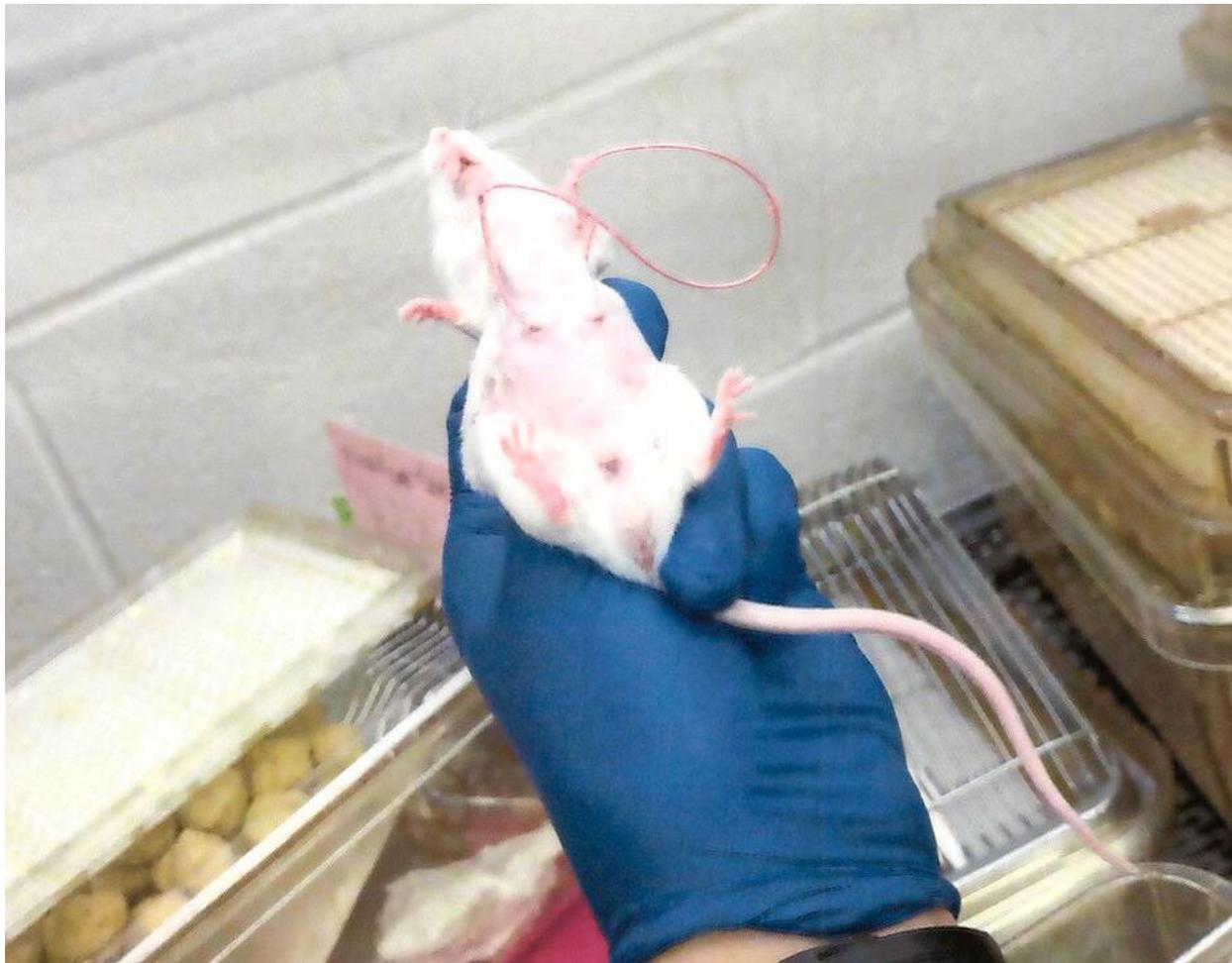
156. Baylor performed an internal investigation and drew no conclusions about the connection between the mouse death and its botched procedures, other than to say that the sudden mouse death was “irrelevant” to the failure to provide postoperative medications as required by the research protocol.

157. Baylor only reported to OLAW that four mice had incomplete surgery cards and did not receive all their post-operative pain medication (half-truths), i.e., a card placed on the outside of the cage with information for the researchers. Baylor further lied

to OLAW, stating that there were “no other health concerns noted” with the mice, and failed to report the deaths.

158. On September 4, 2019, in the same lab, Baylor researchers surgically placed a telemetry lead (a wire) on the exterior body of a mouse instead of inside the mouse’s body, as required by research protocol. The mouse had to be euthanized because of risk that the mouse would chew or tangle the lead in a water bottle and seriously injure itself. Further, the improper placement of the lead rendered the mouse useless for the study.

159. Below is a photo of the mouse with the harmful exterior telemetry lead:



160. However, in violation of federal reporting requirements, Baylor did not report these serious incidents that occurred in “PI-D’s” lab in September. Instead, Baylor made the reports on December 16, 2019. Further, Baylor falsely reported to OLAW that there “were no other health concerns noted” other than “an incomplete surgery card,” i.e., a card placed on the outside of the case with information for the researchers. Baylor made no mention of the mouse’s death or that a second mouse had to be euthanized due to the exposed telemetry lead.

161. Instead of meeting its obligations to report the deaths of both mice, Baylor whitewashed the incident as a harmless one. These omissions misled OLAW and NIH/NHLBI to believe that Baylor was compliant with federal requirements.

162. Had Baylor truthfully reported to the government, a further investigation may have been conducted or directed to determine whether the research data resulting from federally funded studies involving these animals were valid and reliable, and whether grant funding should be suspended or revoked based on the serious and continuing noncompliance.

163. Further, Baylor had already been put on notice by other researchers and veterinary staff who warned that “PI-D’s lab had serious problems such as:

- there was no qualified or “proficient” trainer under the Training Ambassador Program
- at least one researcher who was not qualified or deemed “proficient” had been allowed to conduct surgery.

- another researcher who had performed surgeries was not even approved to conduct research for “PI-D’s” lab, let alone approved to perform surgeries on live animals.

164. Below are further examples where Baylor allowed mice to suffer and die from botched surgeries. In these instances, Baylor failed to take corrective action and chose to not report these deaths to OLAW:

- July 20, 2017 (thereabouts): two mice in “PI-E’s” lab had to be euthanized because a researcher clipped their tails too short, exposing bone and causing pain.
- January 10, 2019: a mouse in “PI-F’s” lab had to be euthanized because a researcher clipped its tail too short, exposing bone and causing pain.
- February 1, 2019: a mouse in “PI-G’s” lab died after it was not provided analgesia; although the failure to provide pain relief was reported to OLAW, Baylor did not report that the mouse died. To the contrary, Baylor lied and said there were “no health concerns observed.” Pain relief and monitoring are also required by internal IACUC procedures.
- June 20, 2019: two mice in “PI-H’s” lab were found to have far exceeded the euthanasia criteria for tumor size and were euthanized later than they should have been, therefore suffering more than necessary. However, Baylor failed to report this serious noncompliance. Instead, it reported to

OLAW that a different case of mice slated for euthanasia in “PI-H’s” lab had experienced overcrowding.

165. Instead of meeting its obligations to report the botched surgeries on mice, Baylor whitewashed these incidents as harmless. These omissions misled the government to believe that Baylor was compliant with federal requirements. Further, Baylor did not take corrective action and allowed these serious problems to continue.

166. Had Baylor truthfully reported to the government, a further investigation may have been conducted or directed to determine whether the research data resulting from federally funded studies involving these animals were valid and reliable, and whether grant funding should be suspended or revoked based on the serious and continuing noncompliance.

167. Through its fraudulent course of conduct, Defendant knowingly submitted or caused the submission of false or fraudulent claims to the government, in violation of the False Claims Act, and the government paid those claims.

**B. Knowledge that the Scheme was Unlawful (Scienter)**

168. Baylor knew that it was required to treat animals humanely before, during and after performing surgical procedures on animals to obtain and retain federal grant monies. Over almost a decade, Baylor was repeatedly flagged as non-compliant and directed to perform multiple internal investigations because animals were not being treated humanely. It was at least twice placed on enhanced reporting in 2013 and 2018.

169. Further, Baylor understood the significance of assuring government agencies that it was engaged in humane animal research, as an OLAW representative reminded Baylor in September 2019, “[i]n order for Baylor to receive money to do animal research ...an assurance must be [in] place ...because ...we have to make sure that this federal money is being spent to conduct the research [surgeries] in a humane fashion.” Further, Baylor was warned that if it did not comply with its Assurance, “there’s no more federal money from NIH to do the animal research” because the funding would be revoked if Baylor failed “to protect the welfare of animals.”

170. Yet, Baylor did not fix its pervasive problems with the government-funded labs, conduct proper investigations or reviews, take seriously its enhanced reporting obligations, or effectuate the corrective actions it repeatedly promised the government.

171. Instead, Baylor continued to falsely certify in its annual reports, Assurances and progress reports to the government that its research on animals was conducted in accordance with animal welfare requirements and based on valid and reliable data.

172. Through its fraudulent course of conduct, Defendant knowingly submitted or caused the submission of false or fraudulent claims to the government, in violation of the False Claims Act, and the government paid those claims.

### **1. Turning a Blind Eye to Repeated Violations**

173. Baylor knowingly turned a blind eye to the repeated violations in its labs, as shown by repeated botched surgeries and surgical procedures, which happened over and over again in the same labs that were funded by government grants. Indeed, it was because

these labs were funded by the government that Baylor turned a blind eye—discontinuing or halting the lab research to correct serious problems would have jeopardized its funding and called into question whether its research was valid and reliable.

174. Below are examples of additional government-funded labs with persistent violations where Baylor knowingly turned a blind eye, choosing to not take the promised correction actions.

175. For only the examples profiled in this Complaint, the labs at issue were responsible for over \$42 million in government funding as reflected by the chart below:

PI	Date of First Known Incident	2016	2017	2018	2019	2020	2021	Total Federal Funds Received Since First Incident
PI-B	4/1/2016	\$ 420,122.00	\$ 452,890.00	\$ 481,979.00	\$ 862,898.00	\$ 835,788.00	\$ 404,658.00	\$ 3,458,335.00
PI-D	8/29/2019				\$1,461,151.00	\$1,111,224.00	\$1,708,381.00	\$ 4,280,756.00
PI-E	7/20/2017				\$ 571,354.00	\$1,109,959.00	\$1,123,253.00	\$ 2,804,566.00
PI-F	10/27/2017		\$1,300,013.00	\$1,065,374.00	\$1,264,080.00	\$1,535,552.00	\$1,914,682.00	\$ 7,079,701.00
PI-G	2/1/2019				\$ 346,719.00	\$ 346,719.00	\$ 346,719.00	\$ 1,040,157.00
PI-H	6/20/2019				\$874,323	\$ 868,746.00	\$ 866,862.00	\$ 2,609,931.00
PI-I	8/18/2017		\$ 722,208.00	\$ 721,694.00	\$ 347,406.00	\$ 332,714.00	\$ 326,629.00	\$ 2,450,651.00
PI-J	4/12/2016*	\$1,210,810.00	\$1,027,746.00	\$ 2,076,126.00	\$ 613,164.00	\$1,073,436.00	\$1,506,354.00	\$ 7,507,636.00
PI-K	Jun-16	\$ 800,980.00	NA	\$ 480,181.00	\$ 598,799.00	\$ 676,342.00	\$ 696,299.00	\$ 3,252,601.00
PI-L	2018**			\$ 813,619.00	\$ 901,598.00	\$1,988,153.00	\$1,770,362.00	\$ 5,473,732.00
PI-M	May-19				\$ 1,147,015.00	\$1,100,147.00	\$ 674,574.00	\$ 2,921,736.00
	*Earliest reported incident							\$ -
	** Did not report incident to OLAW							\$ -
								\$ 42,879,802.00

176. Further, Baylor knowingly omitted in its reports that these serious incidents were recurring in the same labs, including that these incidents were not only **serious** but also **continuing** noncompliance, and worse, often told OLAW that each reported serious incident was a first or isolated incident—these were a combination of outright lies to the government and half-truths.

**a. Example 1**

177. For example, there were serious and continuing noncompliance in the lab headed by “PI-I”, but Baylor withheld material information from OLAW, and refused to implement more stringent monitoring or sanctions even as certain problems escalated.

On April 17, 2018, Baylor reported to OLAW that:

- two mice had died because of “incompletely closed surgical wounds” and not being “observed during recovery from surgery”
- the surgery was performed without proper aseptic technique

178. Although Baylor represented that it was halting all surgeries in “PI-I’s” lab until retraining by a veterinarian and enhanced surgical training was completed, serious incidents in “PI-I’s” lab continued year after year unabated. Further, Baylor failed to report that these serious incidents had occurred eight months earlier, on August 18, 2017.

179. In September 2018, “PI-I’s” lab left anesthetized mice unmonitored on a heating disk during anesthesia induction, a serious violation of protocol that led the attending veterinarian to forbid the researcher from performing surgery on animals involving anesthesia until retrained. But this was the same corrective action required of another researcher in the same lab four months earlier.

180. Baylor never reported this serious and continuing noncompliance to OLAW.

181. On October 4, 2019, Baylor reported to OLAW that an expired drug had been administered during surgery in “PI-I’s” lab. However, it also lied to OLAW, representing that this was “this investigator’s first incident of this nature.”

182. Baylor reported to OLAW that these corrective actions were taken:

- the implementation of “a comprehensive plan ...to ensure appropriate oversight of compliance”
- “increased oversight of the surgeries performed under supervision of the PI[,]”
- requirements to review guidelines for expired drugs and complete training for research personnel
- implementation of “a monthly drug inventory monitoring system”

183. However, Baylor knowingly omitted in its report that these serious incidents were continuing in the same labs, and worse, often told OLAW that each reported serious incident was a first or isolated incident—these were a combination of outright lies to the government and half-truths.

184. Baylor also falsely promised that it would monitor “PI-I’s” lab and apply increased sanctions as necessary: “[i]f compliance with the IACUC approved plan or the increased oversight is not maintained, there will be escalating punitive corrective actions including, but not limited to suspension of all surgical privileges.” Baylor knowingly concealed that there was earlier noncompliance in the lab of “PI-I,” and therefore that this noncompliance was not only **serious** but also **continuing**.

185. Baylor also failed to report that this serious incident occurred in April 2019, six months before it made this report to OLAW.

186. Serious incidents involving “PI-I’s” lab continued unabated even though Baylor had earlier promised OLAW that it had taken corrective action to prevent further violations.

187. Less than five months later, Baylor reported to OLAW that the lab neglected to administer pre-operative pain relief, which it referred to as the “second incident of this nature.”

188. Even though this was a fourth serious incident of botched surgical procedures by “PI-I’s” lab, Baylor did not implement more stringent monitoring or sanctions. Baylor did nothing more than restate corrective action promised earlier and make hollow promises to “further escalat[e] punitive corrective actions.” However, Baylor stopped short of suspending surgical privileges, a remedy available to it.

189. Baylor’s false statements and material omissions to the government relating to “PI-I’s” lab protected Baylor from jeopardizing its receipt of \$2,450,651 in government-funding since 2017.

190. Baylor routinely failed to share that its labs were repeat violators to prevent red flags to OLAW. Had Baylor disclosed that continuing noncompliance was happening at the same government-funded labs, OLAW could have (a) recognized that Baylor was not taking the promised corrective actions, and (b) imposed more stringent requirements or withdrawn federal funding.

191. In summary, the reports and (material) half-truths made to OLAW include these continuing and unabated serious incidents in “PI-I’s” lab, all of which were incidents of serious and continuing noncompliance of federal requirements:

DATE SERIOUS INCIDENT OCCURRED	DATE SERIOUS INCIDENT REPORTED TO OLAW	DESCRIPTION OF SERIOUS INCIDENT	CORRECTIVE ACTION REPORTED TO OLAW	OMISSIONS (HALF-TRUTHS) & LIES TO OLAW
8/18/2017	7 months later, on 4/17/2018	Botched surgeries: 1 mouse found dead; 1 mouse euthanized	Promised to halt surgeries & provide retraining to PI-I's lab	reporting was delayed in this lab ("PI-I's")
9/18/2018 (thereabouts)	Never reported the serious incident	More botched mice surgeries: left an anesthetize mouse alone on a heating disk	Never reported the serious incident	never reported the serious incident; this lab was a repeat violator & it was the second incident i.e., "PI-I's"
4/1/2019 (thereabouts)	6 months later, on 10/4/2019	More botched mice surgeries: administered old/expired drugs to mice during surgeries	Increased oversight & implemented procedures	this lab ("PI-I") was a repeat violator, <b>but</b> instead reported this was the lab's "first incident" instead of third incident; reporting was delayed; not only serious but also <b>continuing</b> noncompliance
12/19/2019	over 2 months later, on 2/28/2020	More botched mice surgeries: no pre-op pain relief	Again promised to provide training and increased oversight	this lab ("PI-I") was a repeat violator, <b>but</b> instead reported this was the lab's "second incident" instead of fourth incident; reporting was delayed

192. Baylor falsely led OLAW to believe that it corrected its problems; however, as shown by the continued noncompliance, corrective action was not implemented to prevent recurrence.

193. Further, noncompliance in the lab of “PI- I” was persistent and well known to Baylor, dating back to at least 2013. For example, in 2013, a Baylor researcher left one mouse alive in a bag containing 32 euthanized mice in a carcass freezer. Yet, even knowing the significant length of time of the noncompliance, Baylor failed to stop the noncompliance or implement measures to prevent future noncompliance.

194. On information and belief, this serious and continuing noncompliance across federal funded studies impacted the validity and reliability of the government-funded research.

**b. Example 2**

195. As another example, there were seven separate incidents of serious and continuing noncompliance in “PI-J’s” lab in less than two years, including two mouse deaths, but Baylor withheld material information about the incidents from OLAW, and refused to implement more stringent monitoring or sanctions even as the noncompliance escalated.

196. Of the seven reported incidents:

- five involved surgeries that were substantially noncompliant
- four involved not providing basic, routine care for animals, in at least one case leading to deaths
- multiple incidents involved administering analgesia improperly
- multiple incidents involved not performing surgeries in a sterile manner
- multiple incidents involved not providing food and water to animals

197. On July 1, 2016, Baylor reported that these violations occurred in one mouse surgery:

- was not performed in a sterile manner
- pre-operative analgesia was not administered
- there was no planning for post-operative pain relief

198. Baylor told OLAW that it took these corrective actions:

- retrained on proper surgical techniques
- retrained on use of surgery cards, i.e., a card placed on the outside of the case with information for the researchers
- reported this incident to the National Institute of Neurological Disorders and Stroke, the funder of this research study

199. Yet, the same problems in “PI-J’s” lab were unabated.

200. On March 15, 2017, Baylor reported to OLAW that (a) a mouse was left alone under sedation—a failure to comply with analgesia protocol and an incident of serious noncompliance with federal requirements, and (b) as corrective action, it advised the researcher on proper monitoring.

201. However, Baylor knowingly reported half-truths to OLAW, leaving out material facts that (a) this serious incident occurred in “PI-J’s” lab, the same lab as the July 1, 2016, serious incident, (b) this was therefore both **serious** and **continuing** noncompliance, (c) both serious incidents involved the improper administration of analgesia during surgery, and (d) prior corrective action had not led to compliance with federal requirements.

202. Yet, the same problems in “PI-J’s” lab were unabated. Only two weeks later, on March 29, 2017, Baylor reported to OLAW that excess acrylic from a cranial procedure was not removed after surgery. Leaving excess acrylic on a mouse could lead to skin tears or get in a mouse’s eyes, presenting a risk of serious harm to the mouse.

Failure to remove this substance from the mouse was a serious and noncompliant federally reportable incident. Baylor told OLAW that as corrective action, it was enforcing the requirement of the lab to use surgical cards.

203. However, Baylor knowingly reported half-truths, leaving out once again material facts that (a) this serious incident occurred in the same lab, (b) enforcing the use of surgical cards with this lab had already been a corrective action previously reported for this same lab, and (c) prior corrective action had not led to compliance with federal requirements.

204. Yet, the same problems in “PI-Js’ lab were unabated and continued even though Baylor earlier and repeatedly had promised OLAW that corrective measures had been implemented.

205. On October 12, 2017, Baylor reported to OLAW that a mouse surgery had not been performed in a sterile manner (improper “aseptic technique”) and that the mouse was not kept warm during the surgery (improper “heat support”) in violation of federal requirements, including research protocol requirements. Baylor told OLAW that as corrective action, it trained staff on proper surgical technique.

206. However, Baylor (again) knowingly reported half-truths, leaving out the material facts that (a) this serious incident occurred in the same lab (“PI-J’s” lab), (b) “retraining” had already been a corrective action previously reported for this same lab, and (c) prior corrective action had not led to compliance with federal requirements.

207. Yet, the same problems in “PI-J’s lab were unabated and continued. On February 6, 2018, Baylor reported to OLAW:

- two mice appeared “moribund” and excessive acrylic was left on their bodies after surgeries
- two other mice were not provided pain relief after surgery and moving in a way that showed they were in pain, one of which had to be euthanized

208. Baylor told OLAW that as corrective action, it trained staff on proper surgical technique. However, Baylor (again) knowingly reported half-truths, leaving out the material fact that: (a) these serious incidents occurred in “PI-J’s” lab—the same lab, and (b) “retraining” had already been the corrective action that Baylor reported more than once for this same lab.

209. To compound these botched surgeries, “PI-J’s” lab also neglected animals under its care, as shown by additional reports of animal neglect to OLAW during the same time, in violation of federal requirements, including research protocol requirements.

210. However, once again, Baylor knowingly failed to report to OLAW that the neglect was occurring in the same lab where cumulative violations were taking place, and OLAW did not have the material facts to connect the dots.

211. On April 12, 2016, Baylor reported to OLAW that four mice had been denied access to food or water during research, in violation of federal requirements, including research protocol requirements. Baylor told OLAW that as corrective action, it enforced the use of special cage cards to ensure researchers would comply with the research protocol, i.e., a card on the cage to identify the start/end times of monitoring to help the researchers stay within the timeframe allowed for the protocol.

212. Yet, the same problems in “PI-Js” lab were unabated and continued. Less than one year later, on March 13, 2017, Baylor reported to OLAW that 36 mice in a satellite facility had “not [been] cared for on two consecutive days” because of preventable staffing failures. Baylor told OLAW that as corrective action, the planned absences of the individual responsible for the care and feeding of animals would be disclosed.

213. However, Baylor knowingly reported half-truths to OLAW, (a) leaving out material facts that mice had previously been denied food and water in “PI-Js” lab, (b) that this was **serious** and **continuing** noncompliance, and (c) that prior corrective action had not led to compliance with federal requirements.

214. Indeed, the same problems in “PI-J’s” lab were unabated. On March 29, 2017, Baylor reported to OLAW cage conditions, including one resulting in three preventable mouse deaths:

- over-housing of mice
- one cage of mice without water
- dirty cages
- no documentation showing whether animals were cared for

215. Baylor told OLAW that as corrective action, the lab would move the animals to a central facility where “members of the veterinary and central animal facility staff could provide close monitoring of animals following procedures and will assist in the daily health care and observation of the animals.”

216. However, Baylor knowingly reported half-truths to OLAW, leaving out the material facts that these troublesome conditions were present in the same lab and that this was the third report of abhorrent cage conditions and lack of animal care, and that prior corrective action had not led to this lab's compliance with federal requirements.

217. Yet, astonishingly, these same troublesome conditions continued unabated in the lab of "PI-J." On October 12, 2017, Baylor reported to OLAW:

- Housing conditions of the mice in the satellite lab were still unhealthy
- food and husbandry supplies were improperly stored
- "general housekeeping issues" persisted

218. Baylor told OLAW that as corrective action, it would close the satellite "as a result of the housing and maintenance conditions which may have affected the health and wellbeing of the mice."

219. However, Baylor knowingly reported half-truths to OLAW and left out material facts, including that (a) these conditions had been earlier present in the same lab, (b) Baylor never enforced the movement of the mice from the satellite lab to a central area even though it had promised to do so in its last report to OLAW, and (c) Baylor knowingly subjected the mice to harmful conditions.

220. Had Baylor made complete and accurate disclosures to OLAW, the government could have escalated sanctions for noncompliance or withdrawn funding to Baylor.

221. In summary, the reports and (material) half-truths made to OLAW include these unabated serious incidents in “PI-J’s” lab, all of which were incidents of **serious** and **continuing** noncompliance of federal requirements:

DATE SERIOUS INCIDENT REPORTED TO OLAW	DESCRIPTION OF SERIOUS INCIDENT	CORRECTIVE ACTION REPORTED TO OLAW	OMISSIONS (HALF-TRUTHS) & LIES TO OLAW
4/12/2016	Inhumane treatment of mice: mice left dehydrated & starving	Promised that PI-J's lab would be more humane	
7/1/2016	Botched mice surgeries: non-sterile, no analgesic used	Promised to provide retraining	this lab ("PI-J") was a repeat violator
3/13/2017	More inhuman treatment of mice: mice left uncared for (no food, water, or general care)	Again promised to be more humane	this lab ("PI-J") was a repeat violator; not only serious but also <b><u>continuing</u></b> noncompliance
3/15/2017	More botched mice surgeries: failed to monitor sedated mouse	Again promised to provide retraining	this lab ("PI-J") was a repeat violator; not only serious but also <b><u>continuing</u></b> noncompliance
3/29/2017	More botched mice surgeries: left mouse with harmful acrylic on its body after surgery; neglected mice leading to 3 deaths	Again promised to be more humane and provide more retraining	this lab ("PI-J") was a repeat violator; falsely promised to move the mice to a central facility for better oversight, but did not follow through
10/12/2017	More botched mice surgeries and in inhuman treatment of mice: non-sterile surgeries, failure to provide necessary post-op care and dirty cages and bad food	Again promised to be more humane and provide more retraining	this lab ("PI-J") was a repeat violator; the mice had not been moved to a central facility as promised
2/6/2018	More botched mice surgeries: improper and inadequate surgery technique that required euthanasia	Again promised to provide retraining	this lab ("PI-J") was a repeat violator;

222. Baylor falsely led OLAW to believe that it corrected its problems; however, as shown by the continued noncompliance, corrective action was not implemented to

prevent recurrence. On information and belief, these numerous violations impacted the validity and reliability of the government-funded research.

223. Through its fraudulent course of conduct, Defendant knowingly submitted or caused the submission of false or fraudulent claims to the government, in violation of the False Claims Act, and the government paid those claims.

## **2. Paying Lip Service to Lab Training**

224. Baylor's training of its lab staff was abysmal for at least a decade and led to many of the violations alleged in the Complaint.

225. In response to Baylor's self-reports of noncompliance—even though reports were half-truths—OLAW told Baylor that it needed to ensure that researchers involved in surgeries on animals were properly qualified, trained and monitored, and Baylor committed to doing so.

226. However, Baylor never acted on those promises, and animals continued to suffer from surgical procedures because researchers were not qualified, trained and monitored. Inexplicably, Baylor leadership impeded its own IACUC when it:

- allowed research protocol approval with only principal investigator confirmation that researchers would be properly trained to conduct surgery prior to performing surgery on animals
- did not mandate a mechanism for the IACUC to determine proper training, qualifications and monitoring

227. In June 2018, OLAW placed Baylor on enhanced reporting because it suspected Baylor was continuing to not comply with regulatory requirements governing the humane treatment of animals. Being placed on enhanced reporting was a warning to Baylor of the government's concern of its continuing noncompliance with federal requirements.

228. To get the government off its back, on July 30, 2018, Baylor reported to OLAW that it took the following steps:

- implemented a programmatic solution to the ongoing surgical noncompliance
- properly oversaw and monitored the animal research program consistent with regulatory requirements
- required that all researchers undergo “enhanced surgical training and demonstration of proficiency through the [existing] Training Ambassador Program” before they were permitted to conduct further surgeries on animals
- required researchers who were deemed non-proficient to undergo retraining and proficiency assessments
- ensured that its “post-approval monitoring process includes a thorough review of training requirement completion, active review of the approved protocol with the PI, and observations of procedures, which include direct observation of surgical and perioperative procedures[.]”

229. Notably, Baylor promised OLAW that “[n]o surgery will be conducted until proficiency is verified.”

230. In fact, Baylor did not implement these measures despite the escalated warnings and Baylor’s promises. Instead, Baylor allowed the same festering problems to persist.

231. Baylor did not use the Training Ambassador Program as intended or promised to OLAW. Baylor falsely promised that its IACUC would ensure that only trained researchers would perform surgeries.

232. Instead, Baylor failed to put into place a system that ensured training prior to surgery and allowed untrained staff to continue to perform surgeries. For example, Baylor reported to OLAW that seven untrained researchers conducted surgeries on live animals on these dates:

- January 14, 2019
- March 20, 2019
- August 16, 2019 (twice)
- November 5, 2019 (twice)
- December 16, 2019

233. The number of untrained researchers who continued to perform surgeries on animals is far higher, on information and belief. However, Baylor kept OLAW completely in the dark about the extent of its continuing noncompliance, all the while paying lip service to OLAW about compliance.

234. Indeed, Baylor continually chose to withhold information from OLAW about the repeat nature of violations. It also refused to implement more stringent monitoring or sanctions even as serious incidents escalated.

235. Through its fraudulent course of conduct, Defendant knowingly submitted or caused the submission of false or fraudulent claims to the government, in violation of the False Claims Act, and the government paid those claims.

### **3. Concealing from OLAW the Finding of its Accreditor**

236. Baylor is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC), which is a private organization comprised of animal care experts that provides accreditation to institutions like Baylor engaged in animal research. It is the only accrediting body that the Public Health Service, a collection of eight agencies under HHS, recognizes.

237. While accreditation is not mandatory, Baylor promised in its Assurance that it was accredited by AAALAC. The individuals who conduct evaluations for accreditation are highly regarded experts in animal care and research, including professors, researchers, and veterinarians. Federal regulations require institutions like Baylor to report to OLAW “any change...that would place the institution in a different category.”

238. Baylor knowingly concealed from OLAW a crucial finding of its accrediting agency when the agency took action to defer Baylor’s accreditation in 2017.

239. From March 13-17, 2017, AAALAC conducted a Baylor site visit and found serious violations of federal requirements and that “serious items of noncompliance were not consistently reported to OLAW.” Further, AAALAC found that Baylor failed to follow through on corrective action plans. For this reason, it deferred Baylor’s accreditation. (Deferred accreditation is where the institution is accredited but must correct the mandatory items and submit written response actions that addresses all the mandatory issues within a couple months from the date of the letter; failure to fully correct the mandatory issues of deferred accreditation will result in probation.)

240. As one such “serious item of noncompliance,” AAALAC found that while Baylor’s IACUC had found (in June 2016) that one of its principal investigators (“PI-K”) had improperly conducted surgeries in violation of federal requirements, including research protocol requirements, Baylor failed to report this finding of noncompliance to OLAW. Specifically, wound clips were not removed from mice within 10 days of their surgeries, and noticeably the animals’ “hair had completely grown back over the wound area and the incisions had healed completely” (the “June 2016 botched wound incident”)

241. Further, AAALAC found that Baylor failed to report to OLAW the IACUC’s findings of “serious noncompliance” in at least eight other incidents over five months, and in at least three of these incidents, there was no documentation to show whether Baylor communicated at all with its principal investigators or imposed sanctions for these violations that occurred in their labs.

242. In response to the AAALAC finding, in late March 2017, Baylor reported the June 2016 botched wound incident to OLAW for the first time, but knowingly

omitted from its report (a) that the serious incident had occurred 9 months earlier, and (b) that its report was based on AAALAC's finding that Baylor had repeated instances of serious noncompliance, which it failed to promptly report to OLAW (including the June 2016 botched wound incident), a material piece of information to OLAW.

243. Baylor further lied to OLAW when it told OLAW that, because of the botched wound incident, it (a) would "immediately" take corrective action to "halt all surgical procedures" and (b) implement additional training and monitoring, even though Baylor knew the botched wound incident had occurred back in June 2016.

244. More specifically, Baylor intentionally downplayed and misled OLAW about the nature, extent and timing of its problems:

- "in the course of a routine self-assessment, we noted some instances where reporting to OLAW of IACUC compliance determinations did not meet internal expectations for timeliness"
- "there was no impact on internal communication of determinations or completion of required corrective actions"
- we "immediately ensured that all determinations were reported as required"
- promised to take corrective action to include revising the process for monitoring and reporting noncompliance, as well as updating the specific responsibilities of personnel required to make those reports

245. Baylor lied and said these findings arose from a routine self-assessment process (which did not even exist) rather than its accrediting agency, which found it

necessary to defer Baylor's accreditation. Because AAALAC does not share its findings or accreditation determinations with the government, OLAW would have no independent way to uncover the information about these findings of repeated noncompliance.

246. Notably, Baylor would not have reported the botched wound incident to OLAW at all, but for the AAALAC finding.

247. Based on Baylor's false representations of having remedied the noncompliance relating to the botched wound incident, on April 12, 2017, OLAW responded that it "understands that measures have been implemented to improve the management and processing of reportable items. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals." Once again, Baylor knowingly duped OLAW.

248. As all the examples alleged in this Complaint demonstrate, even after being placed on deferred accreditation status in 2017 for its failure to report noncompliance to OLAW, Baylor continued to lie and report half-truths to OLAW.

249. Through its fraudulent course of conduct, Defendant knowingly submitted or caused the submission of false or fraudulent claims to the government, in violation of the False Claims Act, and the government paid those claims.

#### **4. Keeping the Funding Spigot Turned On**

250. Baylor knew that OLAW considered the timeliness of self-reports material to its funding decisions. For one thing, federal requirements and OLAW's interpretation of the requirements make it clear that self-reports must be "prompt," even if only

preliminary, followed by a more complete report. Further, OLAW explicitly told Baylor that it should include dates of serious incidents of noncompliance and make preliminary reports, appreciating that a final report would take more time.

251. Yet, Baylor both concealed the dates of serious incidents and other material information in self-reports and often chose to not make timely reports.

252. The fundamental reason that Baylor falsely reported and omitted material information in its reports to OLAW is because Baylor knew that telling the truth would call into question the validity and reliability of its government-funded research and risk that the government would turn off the spigot. It is inexplicable and inexcusable, however, that Baylor made no significant and lasting effort to overhaul its animal research program to become compliant over the last decade or more.

253. In September 2019, OLAW conducted a “site visit” because of “serious non-compliances that have occurred over the last several years.” At that visit, OLAW threatened that if Baylor did not get into compliance, its federal funding could be restricted or revoked: “[i]f we have to do that to protect the welfare of animals, we have done it, and we will do it.”

254. However, once again, Baylor leadership gave short shrift to the concerns expressed by OLAW. The day after the visit, the Director of the IACUC Office circulated an email to staff in the Office and the IACUC, telling them that OLAW had “no observations or issues that made them generally concerned or worried about the operations of the IACUC, animal care, or our research infrastructure.” Even upon direct

threat of funding withdrawal, Baylor did not get its act together and continued to shirk its federal obligations.

255. As a matter of course, and year after year, Baylor knowingly concealed violations of federal requirements that it was required to report and reported half-truths to the government or outright lied to the government. Baylor knew that these violations were material to the government and contrary to written research protocols. A few of the hundreds of examples of material facts that Baylor knowingly concealed from OLAW to avoid turning off the spigot include those identified in this Complaint. More examples are below.

256. In another example, Baylor routinely delayed reporting the suffering and deaths of piglets in the care of the lab headed by “PI-B” and, in at least one instance, delayed reporting for over a year.

257. In 2017, Baylor reported that one expired drug had been used for two years in countless animal surgeries. However, Baylor falsely reported that “there was no indication of reduced potency of the drugs during the procedures” even though no attempt to evaluate the impact was made.

258. In 2018, “PI-L’s” lab did not comply with research protocol requirements to euthanize animals when they reached a humane endpoint, meaning when they suffered beyond scientific justification. Although required, Baylor did not report this to OLAW.

259. In 2019, one lab performed research on animals without a valid protocol. Although required, Baylor never reported this violation to OLAW.

260. In 2019, one lab headed by “PI-M” could not account for zebrafish it left outside the designated study area in violation of federal requirements, including research protocol requirements, and because the fish were unaccounted for, there was a serious question as to whether they had been fed. Although required, Baylor never reported this violation to OLAW.

261. In summary, underpinning Baylor’s fraudulent pattern and practice alleged in this Complaint was its desire to prevent the government from calling into question its research findings and turning off the spigot.

262. Through its fraudulent course of conduct, Defendant knowingly submitted or caused the submission of false or fraudulent claims to the government, in violation of the False Claims Act, and the government paid those claims.

## **V. MATERIALITY**

263. Baylor knew that compliance with the Animal Welfare Act, its implementing regulations, the Guide for the Care and Use of Laboratory Animals, and the Public Health Service Policy, and Baylor’s Assurance that includes a promise to comply with such regulations as a funding requirement, were material to the government’s decision to pay grants for Baylor’s research on living animals. Baylor also knew that truthful reports to OLAW and other government agencies regarding instances of noncompliance, and corrective actions taken, were material to the government’s decision to pay grants for animal research at Baylor.

264. Baylor knowingly falsely certified compliance with these laws and regulations, including requirements that Baylor train its researchers to comply with humane laws and prevent harm to animals during pre- and post- surgical procedures and during surgeries; investigate possible noncompliance; timely and accurately report noncompliance to OLAW and other government funders; and conduct post-approval monitoring to ensure that corrective actions have been taken to prevent continuing noncompliance.

265. Baylor also knowingly submitted false noncompliance reports to the government and used or caused to be used false statements in support of false or fraudulent claims for federal grant money in violation of the False Claims Act.

266. Baylor knowingly submitted false or fraudulent annual reports, Assurances, noncompliance reports, and progress reports to the government, all of which were related to federal grant money, and all of which tainted the federal grant money provided to Baylor for animal research.

267. Each time that Baylor applied for funding, its application included its Assurance, in which it told the government that “[a]ny serious or continuing noncompliance with the PHS Policy . . . and other relevant Federal regulations are reported in writing by the IACUC, through the IO, to OLAW.” Thus, each time that Baylor applied for any federal funding, having knowingly failed to report noncompliance as alleged in this Complaint, it made a false claim to the government. Baylor was aware that these false claims were material to the government’s decision to provide or withdraw funding.

268. The allegations in this Complaint show that Defendant was well aware of all federal requirements, and that it was unlawful to submit false noncompliance reports to the government, and further, that the violations alleged in this Complaint were material to the government's decision to pay federal grant money.

269. Baylor also knew that the unlawful conduct alleged in this Complaint went to the very heart of the bargain for the payment of federal grant money for research. The federal government expects and requires that federal grant money be paid only when the research institution will comply with all relevant statutes and regulations and be truthful regarding any noncompliance, including systematic noncompliance.

270. The government's statutory and programmatic requirements for complete, accurate and truthful reporting during government-funded research go directly to the "essence of the bargain." These requirements are neither "minor nor insubstantial."

271. Baylor's violations of the statutory, regulatory, and programmatic requirements were serious and material, leading to actual and potential harm, and were made with at least reckless disregard of the seriousness of its violations.

272. Baylor's violations were not immaterial or inadvertent technical mistakes in processing paperwork, or simple and honest misunderstandings of the rules, terms and conditions, or certification requirements. Rather, Baylor failed to comply with material legal obligations and certifications. These false submissions undermined the validity, reliability and integrity of the research for which the federal government was paying. For example, as detailed in this Complaint, Baylor knowingly withheld material information from the government when it falsely reported that no mice were harmed after their water

supply was cut off, and several mice died, and others were small and dehydrated. As one Baylor research told the IACUC Chair, such an issue “significantly affects our breeding, our research, and our work.” Thus, Baylor knowingly misled the government regarding the effect that this noncompliance incident might have had on Baylor’s research.

273. Baylor was aware that falsely asserting compliance with federal requirements, including surgical and reporting requirements, would be material to the federal government. OLAW placed Baylor on “enhanced reporting” twice between 2013 and 2018, based on programmatic noncompliance with federal requirements. Upon information and belief, had OLAW been aware of continued noncompliance, it likely would have begun withdrawing federal funding or declining to extend new funding to Baylor for animal research.

274. On April 15, 2013, OLAW placed Baylor on “enhanced reporting” due to the ongoing failure to ensure death after euthanasia and the continuing discovery of live animals in the euthanasia freezer. OLAW noted that the corrective actions that Baylor had implemented would have the impact of **discovering** live animals in the freezer but not of **preventing** incomplete euthanasia. OLAW therefore required Baylor to report monthly, including the number of incidents in which euthanasia was incomplete, information on whether automated euthanasia chambers that would ensure death would be used, and escalating sanctions on researchers or laboratories with repeat occurrences. Thus, Baylor was put on notice that OLAW took these problems very seriously and required it to ensure that methods would prevent incomplete euthanasia. Upon

information and belief, OLAW would have withdrawn funding had Baylor not reported compliance with the federal euthanasia regulatory requirements.

275. On July 11, 2018, OLAW again placed Baylor on “enhanced reporting” due to programmatic noncompliance with surgical requirements. OLAW did so because Baylor had demonstrated “ongoing serious programmatic noncompliance with the PHS Policy” regarding surgery on research animals and needed to be assured that Baylor would implement appropriate systemic improvements so that animal surgeries going forward would be “conducted in a compliant fashion.” Baylor was therefore aware that it had to report noncompliance, and that false reports of compliance, or failing to report noncompliance while asserting to OLAW that it was reporting all noncompliant incidents, was material to OLAW’s decision as to whether to withdraw federal funding or provide new funding.

276. In other cases, OLAW made clear to Baylor that the impact of noncompliance was material. For example, in one case, Baylor reported that nineteen mice were given an experimental drug that was not approved in the research protocol and without scientific justification. OLAW informed Baylor that it could not pay for the unapproved drugs or the procedure using NIH grant funding, and it could not publish the data acquired from the unapproved activity. Therefore, by not reporting noncompliant incidents, and by failing to implement a system by which compliance could be ensured, Baylor knowingly used federal funds in ways it was not entitled and ensured that the NIH would not withdraw that funding.

277. Baylor knew that it was submitting or causing to submit false and fraudulent reports in connection with government-funded grants, including falsely certifying compliance with statutory and regulatory requirements and making false reports regarding individual instances of noncompliance with those statutes and regulations.

278. The DOJ has indicated that it intends to go after such claims. For example, in 2019, the DOJ settled a False Claims Act case with Duke University for \$112.5 million, based on allegations that Duke submitted false claims to the NIH and another government funder related to research on mice, causing the government to pay out grants funds they otherwise would not have paid.

279. In short, there is ample evidence to show that Baylor knew or should have known that its violations had the natural tendency to influence the government's decision to pay federal grant money towards research and that any reasonable person would attach importance to Baylor's choice of action.

## **VI. UNLAWFUL RETALIATION**

280. Relator repeatedly and consistently informed Baylor officials of concerns related directly to the allegations set forth in the Complaint because Relator was troubled that Baylor was engaged in the unlawful practices alleged in this Complaint.

281. Yet, Relator was reprimanded and retaliated against by Baylor officials when raising concerns related to, and objecting to, the patterns and practices alleged in this Complaint.

282. Baylor terminated Relator on October 2, 2019, because of lawful acts by Relator to stop one or more violations of the False Claim Act and lawful acts by Relator in furtherance of an action under 31 U.S.C. § 3730.

283. Below are some specific events that occurred, which are relevant to the retaliation allegations in this Complaint.

284. Relator is highly respected and widely known in the lab animal care community. Relator has authored several scientific articles, speaks often to audiences around the globe and is a past regular contributor to the public outreach column for Lab Animal magazine. She is frequently interviewed by reporters about animal research and laboratory animal care.

285. Relator is also a leading voice in shifting the culture of lab animal care, providing more compassionate ways to approach the topic. Relator holds half a dozen certifications in animal welfare and has received 8 different awards such as “Above and Beyond Award *for dedication above and beyond the call of duty*” from The National Animal Interest Alliance (NAIA), to name just a fraction of the experience and accolades Relator has received over her 20+ year career.

286. Relator is also Chair of Americans for Medical Progress, the president of the Texas Society for Biomedical Research, a past president of the Laboratory Animal Welfare Training Exchange, and past president of the American Association for Laboratory Animal Science, among numerous other affiliations.

287. Relator was hired by Baylor College of Medicine's Center for Comparative Medicine (BCM-CCM) in 2005 as the Associate Director of Training, initially to develop, implement and monitor a rigorous Quality Assurance program that incorporated multiple levels of inspection and peer review aimed at exceeding local and federal regulatory guidelines for research animal care.

288. Relator was promoted to Associate Director of Training and Operations in July 2006 and again to Director of BCM-CCM in July 2011. As Director, Relator oversaw the entire animal care program for the animals involved in research at Baylor. Relator successfully developed, implemented and maintained a comprehensive training and education program for laboratory animal technicians, of all levels, acting as Supervisor and Lead Instructor over the program's delivery for 140+ staff members supporting a diverse range of laboratory animals across multiple buildings. In addition to animal health training, Relator also implemented environmental enrichment, safety and species-specific trainings to name a few of her other accomplishments.

289. Relator also facilitated American Association for Laboratory Animal Science (AALAS) certification for BCM-CCM staff and leadership, none of which had the AALAS certifications common for their level of supervision. Relator personally held classes with all the managers to get them all AALAS certified. She received two promotions, three ascending job titles over an almost 15-year tenure with Baylor, and many glowing annual performance reviews from 2011-2017. She was never disciplined and never spoken to about issues with her leadership abilities or performance prior to her whistleblowing activities.

290. Relator had been concerned about the improper training of researchers for many years. In 2014, the animal rights group Physicians Committee for Responsible Medicine (PCRM) publicly called Baylor out for alleged failure to follow protocol requiring organizations to document their attempt to find a way to conduct proposed research without the use of lab animals, called AWA Policy 12. This prompted a meeting with the Vice President for Research to whom Relator reported, as well as the President of Baylor and Relator. Relator also voiced her concerns about Baylor's failure to ensure that researchers were properly trained prior to conducting surgery. The Baylor President told the Vice President for Research to implement the training protocols that Relator had developed. However, Baylor did not do so, and Relator raised this issue to the IACUC at each subsequent semi-annual meeting since 2014, to no avail.

291. On April 25, 2018, OLAW sent Baylor a letter instructing it to properly train researchers before engaging in surgical procedures. This letter coincided with Relator's growing concerns over the years about issues with staff training, and the fact that Baylor was falsely reporting to OLAW that it was complying with such training requirements. However, the IACUC took no immediate action. On May 12, 2018, Relator, along with 10 other BCM-CCM employees including the Attending Veterinarian (AV) for Baylor penned a letter to the IACUC addressing their ongoing concerns about the noncompliance with the requirement that Baylor ensure researchers were trained before conducting surgical procedures.

292. Relator continued to press the issue to IACUC at a meeting in or around June 2018. However, IACUC still voted against implementing such protocols. Relator

and the Attending Veterinarian sent former Vice President of Research, by then the Institutional Official, several additional correspondences after the June 2018 IACUC meeting asking that he and the IACUC reconsider their position.

293. Over the next 16 months, Relator began to suffer ongoing harassment and retaliation. She regularly heard through the grapevine from other employees that the individual who was next in line to become the Dean of Research/Institutional Officer, and therefore Relator's boss, wanted to find some pretext to push Relator out. Relator was told that an "anonymous complaint" was filed against her for "behavior" during the previously mentioned IACUC meeting, which Human Resources decided not to investigate, but which Relator was still spoken to about. Relator was told that another "anonymous complaint" was filed against her in May 2019, which also was not investigated. Finally, Relator was ultimately terminated on October 2, 2019, in direct nexus to lawful acts by her in furtherance of an action under 31 U.S.C. § 3730.

294. Throughout this time, while Relator engaged in the above referenced meetings, discussions and whistleblower activity, the same individual remained the Dean of Research. However, on September 13, 2019, the new Dean of Research was in place. On October 2, 2019, not three weeks into the new dean's tenure, Relator's employment was terminated without cause. Importantly, the new dean was in several meetings at which Relator voiced her ongoing concerns. There was an additional meeting at which the new Dean took issue with Relator's "behavior." Relator also learned of several conversations the Dean was having with Relator's subordinates about removing her in or around September 2019, which the Dean later confirmed when confronted by Relator.

295. On September 19, 2019, OLAW conducted an on-site visit at Baylor, which Relator was present for. On this site visit, OLAW expressed concerns about IACUC's mandated duties. Relator sent an email to OLAW officials about her concerns with Baylor's animal research program on September 29, 2019. Relator simultaneously notified the Dean that she was submitting this e-mail to OLAW. The next day, on September 30, 2019, the Dean contacted Relator around 4:15 pm asking her to meet at 4:30 pm. Relator had left for the day already, so she was unable to meet with the Dean, and was out sick on October 1, 2019.

296. On the morning of October 2, 2019, Relator was called into a meeting with the Dean and an individual from Employee Relations. Relator was immediately informed that her employment as Director of BCM-CCM was terminated. The prompted explanations given to Relator for her termination were, 1. that the College was attempting to "reorganize;" 2. that the College would like to go in a "different direction;" and 3. that Relator was "not fulfilling her leadership role" within the College. After some probing from Relator, Baylor officials stated, "We need to establish the strongest possible program, and you have built a lot of the tenets of that, but we need to move forward from this position and really look at the business operations..." That is the totality of explanation Relator was given for this unceremonious termination. Finally, as Relator was leaving the room, Baylor officials added, "Just to be clear - you're going to leave today, you're not going to contact your staff, right? And you're not going to engage in disparaging activities?"

297. Relator had never received any type of performance improvement plan, or any otherwise negative performance evaluations. Baylor was clearly attempting to handle Relator's termination in a secretive manner, outside normal policy and procedure for handling disciplinary matters as per the Baylor Progressive Discipline Policy which states that "supervisors or issuing authorities will issue formal progressive discipline warnings to address deficiencies in performance, conduct, or policy violations via the steps outlined below." Steps include: 1. Verbal Counsel; 2. 1<sup>st</sup> Warning; 3. 2<sup>nd</sup> Warning; 4. 3<sup>rd</sup> Warning or Termination. Relator received no formal warnings or counsel prior to her termination, demonstrating that in this instance Baylor acted outside the bounds of normal policy and procedure.

298. It is important to reiterate that since Relator was hired by Baylor in 2005, she had an unblemished record for 13 years. It was only after Relator did her job and her legal duty by repeatedly bringing these serious allegations and failures in the system to the attention of numerous Baylor officials, including the Dean of Research, the IACUC and OLAW, that she was accused of "behavioral" issues leading to her termination. Clearly, Relator's relentless efforts to blow the whistle on wrongdoing were the direct nexus to the termination.

299. For the reasons set forth in this Complaint, Relator is entitled to double the amount of back pay, interest on the back pay and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees, and all other remedies and recompense allowable under 31 U.S.C. § 3730(h).

**VII. COUNTS**

**COUNT I**

**Federal False Claims Act:  
31 U.S.C. § 3729(a)(1)(A)**

300. The allegations in the preceding paragraphs are incorporated by reference.

301. Defendant knowingly presented or caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A).

302. The United States paid for claims that otherwise would not have been allowed.

303. Because of these false or fraudulent claims, Defendant is liable to the United States for incurred damages resulting from such false claims, trebled, plus civil penalties for each violation of the Act, and liable for all other relief authorized by statute.

304. As a result of Defendant's violations, the United States has suffered damages in an amount to be determined at trial.

**COUNT II**

**Federal False Claims Act:  
31 U.S.C. § 3729(a)(1)(B)**

305. The allegations in the preceding paragraphs are incorporated by reference.

306. Defendant knowingly made, used, or caused to be made or used false records or statements material to false or fraudulent claims, in violation of 31 U.S.C. § 3729 (a)(1)(B).

307. The United States paid for claims that otherwise would not have been allowed.

308. Because of these false or fraudulent claims, Defendant is liable to the United States for incurred damages resulting from such false claims, trebled, plus civil penalties for each violation of the Act, and liable for all other relief authorized by the statute.

309. As a result of Defendant's violations, the United States has suffered damages in an amount to be determined at trial.

**COUNT III**  
**Federal False Claims Act:**  
**31 U.S.C. § 3729(a)(1)(G)**

310. The allegations in the preceding paragraphs are incorporated by reference.

311. Defendant knowingly made, used, or caused to be made or used false records or statements material to an obligation to pay or transmit money or property to the Government, or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government, in violation of 31 U.S.C. § 3729 (a)(1)(G).

312. The United States paid for claims that otherwise would not have been allowed.

313. Because of these false or fraudulent claims, Defendant is liable to the United States for incurred damages resulting from such false claims, trebled, plus civil penalties for each violation of the Act, and liable for all other relief authorized by the statute.

314. As a result of Defendant's violations, the United States has suffered damages in an amount to be determined at trial.

**COUNT IV**  
**Retaliation of Relator in Violation of False Claims Act**  
**31 U.S.C. § 3730(h)**

315. The allegations in the preceding paragraphs are incorporated by reference.

316. Relator engaged in lawful acts in furtherance of efforts to stop one or more violations of 31 U.S.C. § 3730.

317. Because of Relator's lawful acts, Relator was subject to retaliation by Defendant.

318. Relator was unlawfully retaliated against by Defendant and for engaging in protected activity, namely for raising, objecting to and refusing to participate in fraudulent conduct alleged in the Complaint.

319. Defendant's retaliation against Relator was a violation of 31 U.S.C. § 3730(h).

320. Because of Defendant's violations of 31 U.S.C. § 3730(h), Relator suffered damages.

321. Relator is entitled to damages sustained as a result of the retaliation, including litigation costs and reasonable attorneys' fees, and all other remedies and recompense allowable under 31 U.S.C. § 3730(h).

322. As a direct and proximate result of Defendant's retaliatory actions, Relator suffered damages and is entitled to all allowable relief under the federal False Claims Act, 31 U.S.C. § 3730(h).

**WHEREFORE**, Relator, on behalf of Relator and the United States, prays:

(a) That the Court enter judgment against Defendant in an amount equal to three times the amount of damages the United States has sustained because of Defendant's actions, plus a civil penalty of any amount within the applicable statutory ranges, for each violation

(b) That Relator be awarded an amount that the Court decides is reasonable for recovering the proceeds of the action, including but not necessarily limited to the civil penalties and damages, on behalf of the United States, which, pursuant to the False Claims Act, shall be at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim if the Government intervenes and proceeds with the action, and not less than 25 percent nor more than 30 percent of the proceeds of the action or settlement of the claim if the Government does not intervene

(c) That Relator receive all relief necessary to make Relator whole for Defendant's violations of 31 U.S.C. § 3730(h)

(d) That the Court order Defendant to award Relator front pay in lieu of reinstatement

(e) That Relator receive an award of two times back pay, including the value of lost benefits and equity

(f) That Relator receive an award of compensatory damages in an amount to be proven at trial for the economic, reputational, and emotional harm Relator experienced as a result of Defendant's unlawful conduct; and

(g) That Relator be awarded all costs and expenses incurred, including reasonable attorneys' fees; and

(h) That the Court order such other relief as is appropriate.

Trial by jury is hereby requested.

Dated: December 9, 2021

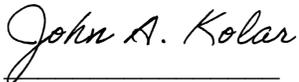
Respectfully submitted,



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