

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (“OIG-HHS”) of the Department of Health and Human Services (“HHS”) (collectively, the “United States”), and Sam W. Lee, PhD (“Dr. Lee”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. During the relevant time, 2014 through 2017, Sam W. Lee, PhD held a dual appointment with Massachusetts General Hospital (“MGH”) and Harvard Medical School. MGH is a recipient of grant funding from the National Institutes of Health (“NIH”), which is part of HHS. MGH was the sponsor institution for Grant No. R01 CA195534-01, titled “p53 survival target DDR1 kinase in DNA damage response and carcinogenesis” (“DDR1 grant”). Dr. Lee served as the Principal Investigator (“PI”) for the DDR1 grant. From March 1, 2015 through June 7, 2018, MGH submitted claims for payment to NIH under the DDR1 grant. MGH received \$939,495.27 in federal funds from the DDR1 grant.

B. Pursuant to NIH policy, PIs are required to provide a signed assurance when submitting a grant application to the NIH. The “assurance must include at least the following certifications: 1) that the information submitted within the application is true, complete and accurate to the best of the PI’s knowledge; 2) that any false, fictitious, or fraudulent statements or claims may subject the PI to criminal, civil, or administrative penalties; and 3) that the PI agrees to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of the application.” NIH Grants Policy

statement 2.3.7.6. On June 25, 2014, Dr. Lee signed the PI assurance for the DDR1 grant application and confirmed that he had reviewed and approved the application.

C. After conducting an internal grant review, MGH stopped drawing federal funds for the DDR1 grant and voluntarily disclosed to the United States that Dr. Lee allegedly submitted grant applications to NIH containing inauthentic data. MGH repaid NIH the full amount of funds it received, \$939,495.27, from the DDR1 grant.

D. The United States contends that Lee caused the submission of claims for payment to NIH.

E. The United States contends that it has certain civil claims against Dr. Lee arising from Dr. Lee's causing the submission of false claims for payment to NIH in connection with the DDR1 Grant, and Dr. Lee's submission of false statements on his grant application for the DDR1 grant, dated June 26, 2014. The United States contends that Dr. Lee knowingly included inauthentic data in his DDR1 grant application to NIH, including figures 6, 7, and 11. Dr. Lee did not conduct the underlying experiments for figures 6, 7, and 11. A fellow in his laboratory conducted the experiments, but no longer worked for Dr. Lee at the time that Dr. Lee submitted the DDR1 grant application. The United States contends that Dr. Lee later altered the experiment descriptions in figure 6 and figure 7, falsifying the results of the experiments, and that Dr. Lee falsified figure 11 by horizontally flipping the image, resulting in the mislabeling of the tissues. That conduct is referred to below as the "Covered Conduct."

F. Dr. Lee agrees not to make or permit to be made any public statement denying, directly or indirectly, any of the Covered Conduct or creating the impression that the Covered Conduct is without factual basis. Nothing in this paragraph affects Lee's: (i) testimonial

obligations; or (ii) right to take legal or factual positions in litigation or other legal proceedings in which the United States is not a party.

In consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Dr. Lee shall pay to the United States the sum of \$215,000, plus interest at a rate of 1.50% per annum from June 28, 2021, and continuing until and including the dates of payment (“Settlement Amount”), of which \$0 is restitution. On the Effective Date of this Agreement, as defined below, this sum shall constitute a debt due and immediately owing to the United States, for which Dr. Lee is liable. Dr. Lee shall pay the Settlement Amount to the United States in installments as follows:

(a) Within seven days of the Effective Date of this Agreement, Dr. Lee shall pay \$100,000, plus interest;

(b) On or before June 28, 2022 Dr. Lee shall pay \$35,000, plus interest accrued on the unpaid balance to date;

(c) On or before June 28, 2023 Dr. Lee shall pay \$40,000, plus interest accrued on the unpaid balance to date; and

(d) On or before June 28, 2024 Dr Lee shall pay \$40,000, plus interest accrued on the unpaid balance to date.

2. Dr. Lee may pay the entire balance of the Settlement Amount, plus interest, or any portion thereof at any time without penalty.

3. Dr. Lee shall make payment of the Settlement Amount by electronic funds transfer pursuant to written instructions to be provided by the United States.

4. Subject to the exceptions in Paragraph 5 (concerning reserved claims) below, and subject to Paragraph 6 (concerning disclosure of assets), Paragraph 11 (concerning default), and Paragraph 12 (concerning bankruptcy) below, and upon the United States' receipt of the Settlement Amount, the United States releases Dr. Lee from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

5. Notwithstanding the release given in Paragraph 4 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, including but not limited to mandatory or permissive exclusion from the Federal health care programs; suspension and debarment rights of any federal agency; and special award conditions and enforcement actions pursuant to, or otherwise consistent with 42 C.F.R. § 52.9, 45 C.F.R. § 75.207, and 45 C.F.R. § 75.213.
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct; and
- e. Any liability based upon obligations created by this Agreement.

6. Dr. Lee has provided financial disclosures and supporting documents (together “Financial Disclosures”) to the United States and the United States has relied on the accuracy and completeness of those Financial Disclosures in reaching this Agreement. Dr. Lee warrants that the Financial Disclosures are complete, accurate, and current as of the Effective Date of this Agreement. If the United States learns of asset(s) in which Dr. Lee had an interest of any kind as of the Effective Date of this Agreement (including, but not limited to, promises by insurers or other third parties to satisfy Dr. Lee’s obligations under this Agreement) that were not disclosed in the Financial Disclosures, or if the United States learns of any false statement or misrepresentation by Dr. Lee on, or in connection with, the Financial Disclosures, and if such nondisclosure, false statement, or misrepresentation changes the estimated net worth set forth in the Financial Disclosures by \$10,750 or more, the United States may at its option: (a) rescind this Agreement and reinstate its suit or file suit based on the Covered Conduct or (b) collect the full Settlement Amount in accordance with the Agreement plus one hundred percent (100%) of the net value of Dr. Lee’s previously undisclosed assets. Dr. Lee agrees not to contest any collection action undertaken by the United States pursuant to this provision, and agrees that he will immediately pay the United States the greater of (i) a ten-percent (10%) surcharge of the amount collected in the collection action, as allowed by 28 U.S.C. § 3011(a), or (ii) the United States’ reasonable attorneys’ fees and expenses incurred in such an action. In the event that the United States, pursuant to this paragraph rescinds this Agreement, Dr. Lee waives and agrees not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that (a) are filed by the United States within 120 calendar days of written notification to Dr. Lee that this Agreement has

been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available prior to January 15, 2021.

7. Dr. Lee waives and shall not assert any defenses Dr. Lee may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

8. Dr. Lee fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Dr. Lee has asserted, could have asserted, or may assert in the future against the United States, and its agencies, officers, agents, employees, and servants related to the Covered Conduct and the United States' investigation and prosecution thereof.

9. Dr. Lee agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Dr. Lee, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;

- (3) Dr. Lee's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);
- (4) the negotiation and performance of this Agreement; and
- (5) the payment Dr. Lee makes to the United States pursuant to this Agreement;

are unallowable costs for government grant and (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Dr. Lee, and Dr. Lee shall not charge such Unallowable Costs directly or indirectly to any grants or contracts with the United States, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Dr. Lee to the United States.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Dr. Lee further agrees that within 90 days of the Effective Date of this Agreement he shall identify and repay by adjustment to future claims for payment or otherwise, any Unallowable Costs included in payments previously sought from the United States, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Dr. Lee, if applicable, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Dr. Lee agrees that the United States, at a minimum, shall be entitled to recoup from Dr. Lee any overpayment plus applicable

interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

If applicable, any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Dr. Lee or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Dr. Lee or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Dr. Lee's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

10. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity.

11. The Settlement Amount represents the amount the United States is willing to accept in compromise of its civil claims arising from the Covered Conduct due solely to Dr. Lee's financial condition as reflected in the Financial Disclosures referenced in Paragraph 6.

a. In the event that Dr. Lee fails to pay the Settlement Amount as provided in the payment schedule set forth in Paragraph 1 above, Dr. Lee shall be in Default of Dr. Lee's payment obligations ("Default"). The United States will provide a written Notice of Default, and Dr. Lee shall have an opportunity to cure such Default within seven calendar days from the date of receipt of the Notice of Default by making the payment due under the payment schedule and paying any additional interest accruing under the Settlement Agreement up to the date of payment. Notice of Default will be delivered to Dr. Lee, or to such other representative as Dr.

Lee shall designate in advance in writing. If Dr. Lee fails to cure the Default within seven calendar days of receiving the Notice of Default and in the absence of an agreement with the United States to a modified payment schedule (“Uncured Default”), the remaining unpaid balance of the Settlement Amount shall become immediately due and payable, and interest on the remaining unpaid balance shall thereafter accrue at the rate of 12% per annum, compounded daily from the date of Default, on the remaining unpaid total (principal and interest balance).

b. In the event of Uncured Default, Dr. Lee agrees that the United States, at its sole discretion, may (i) retain any payments previously made, rescind this Agreement and bring any civil and/or administrative claim, action, or proceeding against Dr. Lee for the claims that would otherwise be covered by the releases provided in Paragraph 4 above, with any recovery reduced by the amount of any payments previously made by Dr. Lee to the United States under this Agreement; (ii) take any action to enforce this Agreement in a new action; (iii) offset the remaining unpaid balance from any amounts due and owing to Dr. Lee by any department, agency, or agent of the United States at the time of Default or subsequently; and/or (iv) exercise any other right granted by law, or under the terms of this Agreement, or recognizable at common law or in equity. The United States shall be entitled to any other rights granted by law or in equity by reason of Default, including referral of this matter for private collection. In the event the United States pursues a collection action, Dr. Lee agrees immediately to pay the United States the greater of (i) a ten-percent (10%) surcharge of the amount collected, as allowed by 28 U.S.C. § 3011(a), or (ii) the United States’ reasonable attorneys’ fees and expenses incurred in such an action. In the event that the United States opts to rescind this Agreement pursuant to this paragraph, Dr. Lee waives and agrees not to plead, argue, or otherwise raise any defenses of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims

that are (i) filed by the United States against Dr. Lee within 120 days of written notification that this Agreement has been rescinded, and (ii) relate to the Covered Conduct, except to the extent these defenses were available prior to January 15, 2021. Dr. Lee agrees not to contest any offset, recoupment, and /or collection action undertaken by the United States pursuant to this paragraph, either administratively or in any state or federal court, except on the grounds of actual payment to the United States.

c. In the event of Uncured Default, OIG-HHS may exclude Dr. Lee from participating in all Federal health care programs until Dr. Lee pays the Settlement Amount, with interest, as set forth above (Exclusion for Default). OIG-HHS will provide written notice of any such exclusion to Dr. Lee. Dr. Lee waives any further notice of the exclusion under 42 U.S.C. § 1320a-7(b)(7), and agrees not to contest such exclusion either administratively or in any state or federal court. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Dr. Lee wishes to apply for reinstatement, Dr. Lee must submit a written request for reinstatement to OIG-HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. Dr. Lee will not be reinstated unless and until OIG-HHS approves such request for reinstatement. The option for Exclusion for Default is in addition to, and not in lieu of, the options identified in this Agreement or otherwise available.

12. In exchange for valuable consideration provided in this Agreement, Dr. Lee acknowledges the following:

a. Dr. Lee has reviewed his financial situation and warrants that he is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I) and shall remain solvent following payment to the United States of the Settlement Amount.

b. In evaluating whether to execute this Agreement, the Parties intend that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to Dr. Lee, within the meaning of 11 U.S.C. § 547(c)(1), and the Parties conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange.

c. The mutual promises, covenants, and obligations set forth herein are intended by the Parties to, and do in fact, constitute a reasonably equivalent exchange of value.

d. The Parties do not intend to hinder, delay, or defraud any entity to which Dr. Lee was or became indebted to on or after the date of any transfer contemplated in this Agreement, within the meaning of 11 U.S.C. § 548(a)(1).

e. If Dr. Lee's obligations under this Agreement are avoided for any reason (including but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code) or if, before the Settlement Amount is paid in full, Dr. Lee or a third party commences a case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors seeking any order for relief of Dr. Lee's debts, or to adjudicate Dr. Lee as bankrupt or insolvent; or seeking appointment of a receiver, trustee, custodian, or other similar official for Dr. Lee or for all or any substantial part of Dr. Lee's assets:

(i) the United States may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against Dr. Lee for the claims that would otherwise be covered by the releases provided in Paragraph 4 above; and

(ii) the United States has an undisputed, noncontingent, and liquidated allowed claim against Dr. Lee in the amount of \$1,878,990.54, less any payments received pursuant to

this Agreement, provided, however, that such payments are not otherwise avoided and recovered from the United States by Dr. Lee, a receiver, trustee, custodian, or other similar official for Dr. Lee.

f. Dr. Lee agrees that any civil and/or administrative claim, action, or proceeding brought by the United States under Paragraph 12.e is not subject to an “automatic stay” pursuant to 11 U.S.C. § 362(a) because it would be an exercise of the United States’ police and regulatory power. Dr. Lee shall not argue or otherwise contend that the United States’ claim, action, or proceeding is subject to an automatic stay and, to the extent necessary, consents to relief from the automatic stay for cause under 11 U.S.C. § 362(d)(1). Dr. Lee waives and shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claim, action, or proceeding brought by the United States within 120 days of written notification to Dr. Lee that the releases have been rescinded pursuant to this paragraph, except to the extent such defenses were available prior to January 15, 2021.

13. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

14. Each Party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

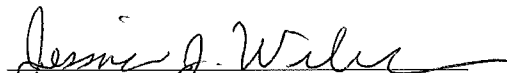
15. This Agreement is governed by the laws of the United States. The exclusive venue for any dispute relating to this Agreement is the United States District Court for the District of Massachusetts. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

16. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.
17. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.
18. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.
19. This Agreement is binding on Dr. Lee's successors, transferees, heirs, and assigns.
20. The Parties may execute this Agreement via facsimile and/or by portable document format (.pdf), both of which shall be deemed the equivalent of an original signature.
21. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.
22. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement).

THE UNITED STATES OF AMERICA

DATED: 8/6/2021

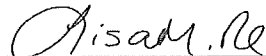
BY:



Jessica J. Weber
Assistant United States Attorney
United States Attorney's Office for the
District of Massachusetts

DATED: 8/06/2021

BY:



Lisa M. Re
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

SAM W. LEE - DEFENDANT

DATED: July 31, 2021

B Sam W. Lee

Sam W. Lee, PhD

DATED: 8/3/21

BY: Tracy A. Miner

Tracy A. Miner
Counsel for Dr. Lee