

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 of the Department of Health and Human Services (collectively, the “United States”), and President and Fellows of Harvard College and its Harvard T.H. Chan School of Public Health (“HSPH”) (collectively, “Harvard”) (hereafter, the United States and Harvard are referred to as “the Parties”), through their authorized representatives.

RECITALS

A. HSPH, located in Boston, Massachusetts, is a graduate level institution engaged in teaching and research as an academic unit of Harvard. Harvard is a recipient of grant funding from the National Institutes of Health (“NIH”) and Health Resources & Services Administration (“HRSA”), both of which are part of the United States Department of Health and Human Services.

B. In May 2016, following an internal review that began in the summer of 2015, Harvard self-disclosed to NIH and the United States Attorney’s Office for the District of Massachusetts inaccuracies relating to (now former) HSPH Professor Donna Spiegelman’s time and effort reporting on several NIH grants. (Hereafter, Professor Spiegelman is referred to as the “faculty member.”) Harvard requested time to more thoroughly investigate the grants management issues it had identified and then to provide additional facts to the government.

C. In October 2017, Harvard supplemented its initial self-disclosure with additional information. Harvard identified practices that resulted in inaccurate submissions to NIH regarding: a) the faculty member’s active and pending research effort; b) the faculty member’s capacity to participate in future grants; and c) discrepancies in time and effort reporting for the faculty member and the members of a research team the faculty member supervised. The time

and effort reporting discrepancies occurred over the course of Harvard's fiscal years 2010 through 2014 (July 1, 2009 – June 30, 2014). Harvard's review focused on a sample group of 12 grants under which the faculty member was active during this time period. The review's findings for the sample group were then extrapolated across all similar grants involving the faculty member during this period, resulting in approximately \$1,359,791.76 in salary costs that were mischarged to federally-sponsored grants. The grants that were either reviewed or subject to the extrapolation are listed on Attachment A. The majority of the inaccurate effort charges related to data analysis performed under NIH grants that funded certain cohort studies being conducted by HSPH. Cohort studies are research projects that gather health data over a period of many years. The faculty member and the faculty member's team provided statistical support on those grants as "Other Personnel." Harvard found, among other things, that the faculty member and the faculty member's team improperly distributed their time and effort across multiple NIH grants related to the cohort studies on a pro rata basis, rather than charging specific amounts of time and effort only to those grants on which they directly worked. Harvard also found that the faculty member overstated a portion of her time and effort on a HRSA-funded President's Emergency Plan for AIDS Relief ("PEPFAR") grant, on which she was Key Personnel. The faculty member did not have documentation sufficient to show what work she completed to justify the salary costs that she charged to the PEPFAR grant.

D. The United States contends that Harvard submitted or caused to be submitted claims for payment to NIH and HRSA.

E. The United States contends that it has certain civil claims against Harvard, arising from the information Harvard disclosed to the United States Attorney's Office and in the factual findings Harvard's University Chief Research Compliance Officer submitted to NIH in February

2018. The factual findings concern NIH and HRSA funded research activity undertaken from 2009 through 2014 at HSPH by the faculty member and those working under her direction. Specifically, the United States contends that, between July 1, 2009 and June 30, 2014 (Harvard's fiscal years 2010 – 2014), Harvard submitted, or caused to be submitted, false claims for: (1) certain charges for the faculty member's time and effort on the HRSA-funded PEPFAR grant listed in Attachment A; and (2) certain charges for the faculty member and her team's time and effort on the NIH grants related to the cohort studies listed in Attachment A. Harvard submitted certifications that overstated the time and effort of the faculty member and her team on these grants because the faculty member and her team had improperly allocated their time and effort across grants related to the cohort studies, instead of allocating their time and effort across grants on which they directly worked. As a result, the faculty member and her team charged to the grants time and effort they could not substantiate, thereby receiving unjustified salary costs from those grants. The United States further contends that Harvard knew or should have known that the manner in which the faculty member, and those working under her direction, were charging time and effort in a manner that resulted in, or would result, in overcharges to these NIH grants. To the extent Harvard, in or around 2011, instructed the faculty member to charge time and effort only to grants on which individuals directly worked (rather than allocating their time across multiple grants funding certain cohort studies), Harvard did not take sufficient steps thereafter to monitor the faculty member's time and effort reporting to ensure that the faculty member and her team followed the proper charging practices. The conduct described in this Paragraph is referred to below as the "Covered Conduct."

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

TERMS AND CONDITIONS

1. Harvard shall pay to the United States one million three hundred fifty-nine thousand seven hundred ninety-one dollars and seventy-six cents (\$1,359,791.76) (“Settlement Amount”), plus interest accruing at an annual simple rate of 1.58% from October 18, 2019, and continuing until and including the day of payment. The Settlement Amount consists of \$1,359,791.76 in restitution. Harvard shall pay the Settlement Amount, plus any accrued interest, to the United States no later than 10 calendar days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by U.S. Attorney’s Office for the District of Massachusetts.

2. Subject to the exceptions in Paragraph 4 (concerning excluded claims) below, and conditioned upon Harvard’s full payment of the Settlement Amount, the United States releases Harvard, together with its governing boards and its constituent parts (schools and allied institutions); its direct and indirect subsidiaries, brother or sister corporations, divisions; and the corporate predecessors, successors and assigns of any of them from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-33, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-12, or the common law theories of payment by mistake, unjust enrichment, and fraud.

3. In consideration of the obligations of Harvard in this Agreement and conditioned upon Harvard’s full payment of the Settlement Amount, the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Harvard under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42

U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 4 (concerning excluded claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Harvard from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 4, below.

4. Notwithstanding the releases given in paragraphs 2 and 3 of this Agreement, or any other term of this Agreement, the following claims 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, including mandatory exclusion from the Federal health care programs; the suspension and debarment rights of any federal agency; or special award condition and enforcement actions pursuant to, or otherwise consistent with 42 C.F.R. § 52.9, 45 C.F.R. §§ 75.207-75.208, or 45 C.F.R. §§ 75.371-75.375.
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement; and
- f. Any liability of individuals.

5. Harvard waives and shall not assert any defenses Harvard 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.

6. Harvard fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including for attorney's fees, costs, and expenses of every kind and however denominated) that Harvard 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.

7. Harvard agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47) incurred by or on behalf of Harvard, and its present or former officers, members of its governing boards, employees, 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) Harvard'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 attorney's fees);

(4) the negotiation and performance of this Agreement;

(5) the payment Harvard makes to the United States pursuant to this Agreement, are unallowable costs for government contracting purposes (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs will be separately determined and accounted for by Harvard, and Harvard shall not charge such Unallowable Costs directly or indirectly to any contract with the United States.

c. Treatment of Unallowable Costs Previously Submitted for Payment:

Within 90 days of the Effective Date of this Agreement, Harvard shall identify and repay by adjustment to future claims for payment or otherwise any Unallowable Costs included in payments previously sought by Harvard or any of its subsidiaries or affiliates from the United States. Harvard agrees that the United States, at a minimum, shall be entitled to recoup from Harvard any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted requests for payment. The United States, including the Department of Justice and/or the affected agencies, reserves its rights to audit, examine, or re-examine Harvard's books and records and to disagree with any calculations submitted by Harvard or any of its subsidiaries or affiliates regarding any Unallowable Costs included in payments

previously sought by Harvard, or the effect of any such Unallowable Costs on the amount of such payments.

8. Harvard agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Harvard shall encourage, and agrees not to impair, the cooperation of the members of its governing boards, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former members of its governing boards, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Harvard further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

9. This Agreement is intended to be for the benefit of the Parties only.

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

11. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

12. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and 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.

13. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

14. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

15. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

16. This Agreement is binding on Harvard's successors, transferees, heirs, and assigns.

17. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.


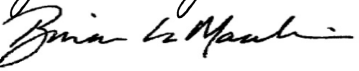
18. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

[Signature Page and Attachment A Follow]

THE UNITED STATES OF AMERICA

DATED: 4/27/2020

BY:

BRIAN M. LAMACCHIA
JESSICA J. WEBER

Assistant United States Attorneys
U.S. Attorney's Office for the District of Massachusetts

DATED: 04/24/2020 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

HARVARD

DATED: 4/18/2020

BY:



Michelle A. Williams, ScD
Harvard T.H. Chan School of Public Health

DATED: 4/20/2020

BY:




MICHAEL K. FEE
CHRISTINE SAVAGE
Counsel for the Harvard T.H. Chan School of Public Health

DATED: 4/17/2020



BY:



Diane E. Lopez, Vice President and General Counsel
President and Fellows of Harvard College

DATED: 4/20/2020

BY:

MICHAEL K. FEE
CHRISTINE SAVAGE
Counsel for the President and Fellows of Harvard College

ATTACHMENT A

PEPFAR Grant

Grant	Grant No.
Rapid Expansion of Antiretroviral Therapy Programs	6U51HA02522-08-12

Cohort Study Grants

Grant	Grant No.
Prospective Study of Restless Legs Syndrome	1 R01 NS062879-01A2
Prospective Study of Vitamin D and Multiple Sclerosis	5R01NS046635-07Revised
Urate as a Predictor of Parkinson's Disease Risk and Progression	5R01NS061858-05Revised
Vitamin D, Epstein-Barr virus infection, and cigarette smoking and risk of multiple sclerosis among women in the Finnish Maternity Cohort and their offspring	5R01NS073633-05
Type 2 Diabetes and Sexual Orientation Disparities in Women	1 R01 DK099360-01A1
Cancer Center Support Grant (46HSPH-S5)	2P30CA-006516-49
Circulating Fatty Acids and Breast Cancer Risk: A Prospective Study	1 R01 CA 160246 - 01 A1
Malaria in Pregnancy: Nutrition and Immunologic Effects	3R01HD057941-05S1
Premenopausal Hormone Levels and Risk of Breast Cancer	5R01CA067262-16Revised
Dietary Patterns and Risk of Cardiovascular Disease	4R01HL060712-15
Dietary Patterns and Risk of Cardiovascular Disease	5R01HL060712-11Revised
Immunology, Inflammation and Endometriosis	1 R01 HD 057210-01A1
Fatty Acids and Major Cardiovascular Outcomes	5R01HL085710-05
Mercury, Selenium, and Risk of Cardiovascular Disease in Women and Men	5R01ES014433-05
Cancer Center Support Grant (HSPH-51)	P30 CA006516
Pooling of Prospective Studies of Diet, Lifestyle and ALS	5R01NS072494-03
Dietary Etiologies of Heart Disease	5R01HL035464-25Revised

Grant	Grant No.
Endothelial Dysfunction, Oxidative Stress, and Risk of Peripheral Arterial Disease (1023686)	1R01HL091874-01A1
Validity of Diet and Activity Measures in Men	5U01CA152904-04Revised
Dietary Polyphenols, Urinary Biomarkers and Risk of Type 2 Diabetes	5R01DK082486-03
Cancer Epidemiology Cohort in Male Health Professionals	5UM1CA167552-04Revised
Life Course Cancer Epidemiology Cohort in Women	4UM1CA176726-04
Prospective Studies of Diet and Cancer in Men and Women	5U19CA055075-20Revised
Prospective Studies of Diet and Cancer in Men and Women	3P01CA055075-18S1
Risk Factors for Breast Cancer in Younger Nurses	5R01CA050385-25Revised