

SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement ("Agreement") is made and entered into by and 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, including the National Institutes of Health ("NIH") ("HHS") (collectively, the "United States"), President and Fellows of Harvard College ("Harvard"), and Beth Israel Deaconess Medical Center ("BIDMC") (hereinafter referred to as "the Parties"), through their authorized representatives.

II. PREAMBLE

WHEREAS, during approximately 1993 through 1998, the National Institutes of Health awarded the following four federal grants (collectively, the "Four NIH Grants") to Harvard:

- Mentored Clinical Scientist Development Program Award, NIH Grant No. K12 AG00294, Grant Years 10, 11, 12, and 13 (the "K12 Grant");
- T-32 Training Grant, NIH Grant No. AG 00251, Grant Years 1, 2, and 3 (the "T-32 Grant");
- Claude Pepper Center Award, NIH Grant No. 08812, Grant Years 7, 8, and 9 (the "Pepper Grant"); and
- Nathan Shock Centers of Excellence in Basic Biology of Aging Award, NIH Grant No. AG 13314, Grant Years 1, 2, and 3 (the "Nathan Shock Grant");

WHEREAS, the NIH awarded Harvard federal grant monies pursuant to the Four NIH Grants, and Harvard charged NIH approximately \$5.5 million in direct and indirect costs related to the grant awards during the years in question;

WHEREAS, under an informal agreement between Harvard and BIDMC, BIDMC performed certain work and incurred certain expenses in connection with the Four NIH Grants; BIDMC submitted invoices to Harvard requesting reimbursement for the work and expenses; and Harvard paid BIDMC and charged these expenses to the four NIH Grants;

WHEREAS, the same individual was the Principal Investigator ("PI") on the K12 Grant, the T-32 Grant, and the Pepper Grant during the above-referenced Grant Years, and was the Research Development Core Director (and, for one year, the PI) of the Nathan Shock Grant during the above-referenced Grant Years; the PI held a faculty appointment at Harvard Medical School and was also employed by BIDMC; and the PI had overall responsibility for the work performed under the K12 Grant, the T-32 Grant, the Pepper Grant, and the Research Development Core of the Nathan Shock Grant, and signed NIH Grant applications and caused them to be submitted to NIH;

WHEREAS, in or about 1999 Harvard initiated certain audit activities regarding the K12 Grant, and in November 1999 and thereafter Harvard and BIDMC retained auditors to review records concerning the K12 Grant, and thereafter Harvard and BIDMC voluntarily disclosed to the United States information concerning results of the audit

activities with respect to the K12 Grant, and the United States thereafter undertook a further investigation of substantially all financial records concerning the K12 Grant;

WHEREAS, in or about 2000 Harvard and BIDMC retained auditors to review records relating to the T-32 Grant, the Pepper Grant, and the Nathan Shock Grant, and Harvard and BIDMC thereafter voluntarily disclosed to the United States information concerning results of the audit activities with respect to the administration of the T-32 Grant, the Pepper Grant, and the Nathan Shock Grant;

WHEREAS, with respect to the K12 Grant, the United States contends that on or about October 27, 1994, June 5, 1996, and September 23, 1997, Harvard submitted grant applications containing incorrect or overstated information about the budgets for the grant years, the physician scientists working on the grant, and the oversight of the progress and administration of the K12 Grant; and the United States further contends that between August 1994 and June 1999, BIDMC submitted invoices to Harvard for, and Harvard charged to the K12 Grant, certain expenses that were not properly chargeable to the K12 Grant, including:

- salary expenses, including salaries of physician scientists who did not work on the K12 Grant, salaries of physician scientists who did not meet the citizenship requirements of the K12 Grant, the salary of a physician scientist who did not meet the 75 percent effort requirement of the K12 Grant, and salary expenses of the Principal Investigator in excess of the budgeted amount;
- supply and equipment expenses, including expenses incurred in connection with other projects not related to the K12 Grant, and expenses incurred by

physician scientists who were not eligible to work on the grant or did not work on the grant;

- expenses related to the use of research animals that were used for other projects not related to the K12 Grant or were used by physician scientists who were not eligible to work on the K12 Grant;

WHEREAS, with respect to the T-32 Grant, the United States contends that between July 1996 and April 1999, BIDMC submitted invoices to Harvard for, and Harvard charged to the T-32 Grant, certain expenses that were not properly chargeable to the T-32 Grant, including salaries of trainees who did not work on the T-32 Grant, or whose Statements of Appointment were not timely filed with the NIH, or who did not meet the citizenship requirements of the T-32 Grant, and including supply and equipment expenses incurred by persons who did not work on the T-32 Grant (the "T-32 Grant Conduct");

WHEREAS, with respect to the Pepper Grant, the United States contends that between March 1996 and February 1999, Harvard charged to the Pepper Grant certain salary expenses and other expenses that were not incurred under the Pepper Grant but were incurred in connection with work done under other grants, and charged certain other expenses and salary charges that were not supported with adequate documentation demonstrating that the expenses were actually incurred under the grant (the "Pepper Grant Conduct");

WHEREAS, with respect to the Nathan Shock Grant, the United States contends that between July 1996 and June 1999, BIDMC submitted invoices to Harvard for certain

expenses incurred in connection with other grants (principally the K12 Grant) or grant cores, and that Harvard improperly charged these expenses to the Nathan Shock Grant (the "Nathan Shock Grant Conduct");

WHEREAS, in or about August 2002, Harvard reached a partial compromise with the NIH with regard to the Covered Conduct, by which Harvard agreed to pay \$850,188 toward the FY 2003 funding of an NIH award made to Harvard;

WHEREAS, the United States contends that it has certain civil claims against Harvard and BIDMC under the False Claims Act, 31 U.S.C. §§ 3729-3733, other federal statutes and/or common law doctrines, for the K12 Grant, the T-32 Grant Conduct, the Pepper Grant Conduct, and the Nathan Shock Conduct described above (hereinafter collectively referred to as the "Covered Conduct").

WHEREAS, Harvard and BIDMC deny as a matter of law that they have any institutional liability under the False Claims Act, 31 U.S.C. §§ 3729-3733, other federal statutes and/or common law doctrines with regard to the Covered Conduct; and

WHEREAS, in order to avoid the delay, uncertainty, inconvenience and expense of protracted litigation of these claims, the Parties reach a full and final settlement pursuant to the terms and conditions as set forth below.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in consideration of the mutual promises, covenants, and obligations set forth below, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. The obligations set forth herein between Harvard and the United States, and between BIDMC and the United States, shall apply independently of one another. Any breach of an obligation between Harvard and the United States shall not affect any obligation between BIDMC and the United States. Any breach of an obligation herein between BIDMC and the United States shall not affect any obligation between Harvard and the United States.

2. Harvard agrees to pay to the United States \$1,319,451 plus interest on such amount at the rate specified at 28 U.S.C. § 1961, from March 19, 2004, to the date of payment ("Harvard's Settlement Amount"), as follows: Harvard agrees to make payment of Harvard's Settlement Amount by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney's Office, District of Massachusetts. Harvard agrees to make this electronic funds transfer by no later than ten business days after the Effective Date of this Agreement or after receipt of the written instructions, whichever is later.

3. BIDMC agrees to pay to the United States \$1,084,819 plus interest on such amount at the rate specified at 28 U.S.C. § 1961, from March 29, 2004, to the date of

payment ("BIDMC's Settlement Amount"), as follows: BIDMC agrees to make payment of BIDMC's Settlement Amount by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney's Office, District of Massachusetts. BIDMC agrees to make this electronic funds transfer by no later than ten business days after the Effective Date of this Agreement or after the receipt of the written instructions, whichever is later.

4. Subject to the exceptions in Paragraph 8 below, in consideration of the obligations of Harvard set forth in this Agreement, conditioned upon Harvard's payment in full of Harvard's Settlement Amount, the United States (on behalf of itself, its officers, agents, agencies and departments) fully and finally releases Harvard, together with its current or former subsidiaries, affiliates, officers, directors, faculty, employees and agents and the successors and assigns of any of them (but specifically excluding Dr. Jeanne Wei), from any civil or administrative monetary claim the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; any statutory provision applicable to the Four NIH Grants for which the Civil Division, Department of Justice has actual and present authority to assert and compromise pursuant to 28 C.F.R. Part O, Subpart I, 0.45(d)(1995); or the common law theories of fraud, payment by mistake, unjust enrichment, breach of contract, disgorgement, recoupment, and conversion.

5. In consideration of the obligations of Harvard set forth in this Agreement and conditioned upon Harvard's payment in full of Harvard's Settlement Amount, the HHS fully and finally releases and agrees to refrain from instituting, directing or maintaining any administrative claim or any suspension or debarment action under 45 C.F.R. Part 76 and 48 C.F.R. Part 9.4, or a fiscal disallowance action against Harvard, together with its current or former subsidiaries, affiliates, officers, directors, faculty, employees and agents and the successors and assigns of any of them (but specifically excluding Dr. Jeanne Wei), for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 8, below. Nothing in this Paragraph shall preclude HHS from imposing special award conditions pursuant to 45 C.F.R. § 74.14. Nothing in this paragraph shall preclude the United States or HHS from taking action against entities or persons, or for conduct and practices, not covered by this paragraph or for which civil claims have been reserved in Paragraph 8 below.

6. Subject to the exceptions in Paragraph 8 below, in consideration of the obligations of BIDMC set forth in this Agreement, conditioned upon BIDMC's payment in full of BIDMC's Settlement Amount, the United States (on behalf of itself, its officers, agents, agencies and departments) fully and finally releases BIDMC, together with its current or former subsidiaries, affiliates, officers, directors, employees and agents and the successors and assigns of any of them (but specifically excluding Dr. Jeanne Wei), from any civil or administrative monetary claim the United States has or may have for the

Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; any statutory provision applicable to the Covered Conduct for which the Civil Division, Department of Justice has actual and present authority to assert and compromise pursuant to 28 C.F.R. Part O, Subpart I, 0.45(d) (1995); or the common law theories of fraud, payment by mistake, unjust enrichment, breach of contract, disgorgement, recoupment, and conversion.

7. In consideration of the obligations of BIDMC set forth in this Agreement and conditioned upon BIDMC's payment in full of BIDMC's Settlement Amount, the HHS fully and finally releases and agrees to refrain from instituting, directing or maintaining any administrative claim or any suspension or debarment action under 45 C.F.R. Part 76 and 48 C.F.R. Part 9.4, or a fiscal disallowance action against BIDMC, together with its current or former subsidiaries, affiliates, officers, directors, faculty, employees and agents and the successors and assigns of any of them (but specifically excluding Dr. Jeanne Wei), for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 8, below. Nothing in this Paragraph shall preclude HHS from imposing special award conditions pursuant to 45 C.F.R. § 74.14. Nothing in this paragraph shall preclude the United States or HHS from taking action against entities or persons, or for conduct and practices, not covered by this paragraph or for which civil claims have been reserved in Paragraph 8 below.

8. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Harvard and BIDMC) are any and all of the following:

- (1) Any civil, criminal or administrative liability under Title 26, U.S. Code (Internal Revenue Code);
- (2) Any criminal liability;
- (3) Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs and Federal grant programs;
- (4) Any liability to the United States (or its agencies) for any conduct other than that arising from the Covered Conduct;
- (5) Any liability based upon such obligations as are created by this Agreement;
- (6) Any claims against Dr. Jeanne Wei.

9. Harvard and BIDMC each waives and will not assert those defenses it may have to any criminal prosecution or administrative action relating to the Covered Conduct, which defenses are 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 or that this

Agreement is punitive in purpose or effect. Nothing in this Paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

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

11. Harvard and BIDMC each agrees to the following:

(a) Unallowable Costs Defined: That all costs (as defined in 45 C.F.R. § 74.27; 45 C.F.R. Part 74, Appendix E; 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. §§ 1395-1395ggg and 1396-1396v, and the regulations and official program directives promulgated thereunder) incurred by or on behalf on Harvard and BIDMC, their present or former officers, directors, employees, shareholders, and agents in connection with the following shall be "unallowable costs" on Government grants and contracts with the United States:

(1) the matters covered by this Agreement,

- (2) the United States' audit(s) and civil and criminal investigations(s) of the matters covered by this Agreement,
- (3) Harvard's and BIDMC's investigation, defense, audits, and any corrective actions undertaken in response to the United States' audit(s) and civil or criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees),
- (4) the negotiation and performance of this Agreement, and
- (5) the payments Harvard and BIDMC make to the United States pursuant to this Agreement, including any costs and attorney's fees.

Nothing in this sub-paragraph affects the status of costs that are not allowable based on any other authority applicable to Harvard and BIDMC. (All costs described or set forth in this Paragraph 10(a) are hereafter, "unallowable costs").

(b) Future Treatment of Unallowable Costs: These unallowable costs shall be separately determined and accounted for by Harvard and BIDMC, and Harvard and BIDMC shall not charge such unallowable costs directly or indirectly to any contracts with or grants from the United States, or seek payment for such unallowable costs through any cost report, cost statement, information statement, or payment request submitted by Harvard or BIDMC or any of their subsidiaries to HHS.

(c) Treatment of Unallowable Costs Previously Submitted for Payment: Harvard and BIDMC further agree that within 20 days of the Effective Date of this Agreement, it

shall identify to NIH, and, if appropriate, to the Centers for Medicare and Medicaid Services, any unallowable costs (as defined in this Paragraph) included in payments previously sought from the United States, including, but not limited to, payments sought in grant applications, grant awards, cost reports, cost statements, information reports, or payment requests already submitted by Harvard or BIDMC or any of their respective subsidiaries, as appropriate, and shall request, and agree, that such grant applications, grant awards, 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. Harvard and BIDMC each agree that the United States, at a minimum, shall be entitled to recoup from Harvard and BIDMC, as appropriate, any overpayment plus applicable interest and penalties as a result of the inclusion of such unallowable costs on previously-submitted grant applications, grant awards, cost reports, information reports, cost statements, or request for payment. Any payment 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 Harvard and BIDMC or any of their subsidiaries on the effect of inclusion of unallowable costs (as defined in this Paragraph) on Harvard or BIDMC or any of their subsidiaries' cost reports, cost statements, or information reports. Nothing in this Agreement shall constitute a waiver of the rights of the United States to examine or reexamine the unallowable costs described in this Paragraph.

12. Harvard and BIDMC each covenants to cooperate fully and truthfully with the United States' investigation of individuals and entities not specifically released in this Agreement, for the Four NIH Grants. Upon reasonable notice, Harvard and BIDMC will make reasonable efforts to facilitate access to, and encourage the cooperation of, their directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals, and shall furnish to the United States, upon reasonable request, all non-privileged documents and records in its possession, custody or control relating to the Four NIH Grants.

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

14. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement shall be the United States District Court for the District of Massachusetts.

15. This Agreement represents the full, complete, and sole agreement between the Parties with regard to the matters contained herein. This Agreement may not be amended except by written consent of the Parties.

16. The undersigned individuals signing this Agreement on behalf of Harvard and BIDMC represent and warrant that they are authorized by Harvard and BIDMC,

respectively, to execute this Agreement. The undersigned United States signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.

17. The parties have executed three identical copies of this Agreement, each of which shall be deemed an original of this Agreement. This Agreement may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same Agreement.

18. The "Effective Date" of this Agreement shall be the earlier of (a) payment by both Harvard and BIDMC of their respective Settlement Amounts, (b) issuance by the NIH of a letter reflecting final resolution of administrative compliance issues with Harvard, or (c) June 17, 2004. This Agreement shall be binding and irrevocable upon the date of signature of the last signatory to this Agreement. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

IN WITNESS WHEREOF, the parties have executed this Agreement.

UNITED STATES OF AMERICA

By: _____
GEORGE B. HENDERSON, II
Assistant U.S. Attorney
District of Massachusetts

Dated: _____

By: _____ Dated: _____
MARC WEISMAN
Deputy Assistant Secretary for
Grants and Acquisition Management
Department of Health and
Human Services

By: _____ Dated: _____
LEWIS MORRIS
Chief Counsel to the Inspector General
Department of Health and
Human Services

PRESIDENT AND FELLOWS OF HARVARD COLLEGE

By: _____ Dated: _____
ERIC BUEHRENS
Executive Dean for Administration
Harvard Medical School

BETH ISRAEL DEACONESS MEDICAL CENTER

By: _____ Dated: _____
PAUL F. LEVY
President and Chief Executive Officer