

## SETTLEMENT AGREEMENT

### I. PARTIES

This Settlement Agreement (Agreement) is entered into between the following (hereinafter collectively referred to as "the Parties") through their authorized representatives: the United States of America, acting through the United States Department of Justice and on behalf of the National Institutes of Health (NIH), the Office of Acquisition Management and Policy of the Department of Health and Human Services (HHS), and the Office of Inspector General of HHS (OIG-HHS)(collectively the "United States"); Johns Hopkins University (the University); Johns Hopkins Bayview Medical Center ("Bayview"); Johns Hopkins Bayview Physicians, P.A. ("JHBP")(collectively referred to as "Johns Hopkins"); and Faye Grau (Relator).

### II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A. The University is a private not-for-profit entity, and its main campus is located in Baltimore, Maryland. The University maintains a School of Medicine, and faculty members may also provide clinical medical services through professional associations affiliated with the University. Johns Hopkins, through its faculty members and other employees, and employees of affiliated entities, conducts medical research through a number of

affiliated entities, and at various sites, including Bayview. Johns Hopkins submits, or has submitted, claims for payment to, or contracts or has contracted with, NIH and other agencies of the United States Government for the purpose of conducting clinical or medical research funded wholly or in part by federal funds.

B. Relator is an individual residing in Maryland. In May, 1999, Relator filed a qui tam action in the District of Maryland entitled United States ex rel. Faye Grau v. Johns Hopkins University School of Medicine, et al., Civil No. CCB-99-1448 (hereafter "the Civil Action").

C. The NIH Office of Management Assessment, Division of Program Integrity performed an audit of various clinical and medical research grants awarded to Johns Hopkins and funded wholly or in part by Federal monies (hereafter "the Grants at Issue"). As a result of this audit, the United States contends that it has certain civil claims against Johns Hopkins, as specified in Paragraph III.C. below, under the False Claims Act, 31 U.S.C. §§ 3729-3733, other federal statutes and/or common law doctrines, for engaging in the following conduct, in connection with the Grants at Issue:

(1) in completing applications for research grants sponsored by NIH or other agencies of the United States Government, or in drawing down funds on such grants, overstating the percentage of effort that personnel would work or had worked on the grant (by,

for example, failing to properly take into account the total activities of the personnel), or using erroneous fringe benefit amounts for research personnel employed by JHBP;

(2) failing to maintain adequate compliance mechanisms to reconcile proposed effort commitments with actual effort devoted to the grants or to charge correct fringe benefit amounts, as required by federal regulations;

(3) in drawing down funds on research grants, basing claims on calculations of personnel costs through the use of documents that could not reliably be used to estimate the percentage of a researcher's or administrator's effort that was devoted to a particular federally-funded research grant; and

(4) in completing applications for addiction services programs funded in part by federal monies, or in drawing down funds in connection with such programs, overstating the amount of effort that personnel would work or had worked on the program (by, for example, failing to properly take into account the total activities of the personnel), or using erroneous fringe benefit amounts for personnel employed by JHBP.

Hereafter, the conduct described in this paragraph II.C., which the United States contends misled the United States into paying more money than Johns Hopkins was lawfully entitled to receive, is collectively referred to as "the Covered Conduct." The Covered Conduct relates to the period January 1, 1994 through

December 31, 2000, except with respect to the matters referenced in paragraph II.C.(4), which relate to the period January 1, 1994 through June 30, 1999.

D. The United States also contends that it has certain administrative claims against Johns Hopkins for engaging in the Covered Conduct, as specified in Paragraph III.D. and III.E. below.

E. Johns Hopkins denies the contentions of the United States as set forth in Paragraph II.C. above and the allegations of the Relator in the Civil Action, and denies that it has any liability relating to these allegations.

F. This Agreement does not constitute an admission by Johns Hopkins of any liability or wrongful conduct, nor evidence thereof, nor a concession by the United States that its claims are not well founded.

G. To avoid the delay, uncertainty, inconvenience and expense of protracted litigation of the claims set forth above, the Parties hereby reach a full and final settlement of the aforementioned claims pursuant to the Terms and Conditions 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:

A. Johns Hopkins agrees to pay to the United States the sum of Two Million Six Hundred Sixty Four Thousand One Hundred Thirty Five Dollars (\$2,664,135.00) (the "Settlement Amount"). The Settlement Amount will be reduced by Five Hundred Eighty Seven Thousand Two Hundred Seventy Three Dollars (\$587,273.00) as credit for refunds already voluntarily paid by Johns Hopkins and attributable to the Covered Conduct for the grants at issue. Johns Hopkins agrees to pay the remainder of the Settlement Amount, Two Million Seventy Six Thousand Eight Hundred Eighty Two Dollars (\$2,076,882.00) by a single electronic funds transfer pursuant to written instructions to be provided by the United States Department of Justice. Johns Hopkins agrees to make this electronic funds transfer within ten (10) business days after its receipt of a fully executed copy of this Settlement Agreement and written electronic funds transfer instructions, whichever occurs last.

B. The United States agrees that, pursuant to 31 U.S.C. § 3730(d)(1), the Relator's share of the Settlement Amount is 16.5 percent of the Settlement Amount. The United States agrees that within a reasonable time after it receives payment of the Settlement Amount, but not until it receives a signed Joint Stipulation of Dismissal document from Relator pursuant to Paragraph III.S. below, the United States will pay to Relator an amount equal to 16.5 percent of the Settlement Amount, or \$439,582.00 (Four Hundred Thirty Nine Thousand, Five Hundred Eighty

Two Dollars). Payment to Relator under this Agreement shall be made by electronic funds transfer in accordance with the written instructions of Relator's counsel.

C. In accordance with 31 U.S.C. § 3730(d), at the same time that it pays the Settlement Amount to the United States, Johns Hopkins shall convey to Relator's counsel, pursuant to Relator's counsel's written instructions, reasonable attorneys' fees and expenses incurred in connection with the Civil Action as agreed to separately between Johns Hopkins and Relator's counsel. This payment of attorneys' fees is in addition to, and not included within, the Settlement Amount payment that Johns Hopkins is making pursuant to this Agreement. Relator represents that her counsel in the Civil Action is Robin Page West, and Relator hereby agrees to hold Johns Hopkins harmless from any claims by others to a share of said attorneys' fees and expenses.

D. Subject to the exceptions in Paragraph III.F. below, in consideration of the obligations of Johns Hopkins set forth in this Agreement, and conditioned upon Johns Hopkins's payment in full of the Settlement Amount, the United States (on behalf of itself, its officers, agents, agencies and departments) agrees to release and hereby does release Johns Hopkins, its current and former physician and non-physician employees, trustees, officers, administrators and other employees, faculty, agents and affiliates (the "Released Entities and Individuals") from any civil or

administrative monetary claim the United States has or may have for the Covered Conduct for the Grants at Issue 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, restitution, recoupment, breach of contract, conversion and fraud. To the extent that any of the Grants at Issue received funding from both Federal and non-federal sources, this Release covers only the Federal portion of the grant amount.

E. In consideration of the obligations of Johns Hopkins set forth in this Agreement, and conditioned upon Johns Hopkins's payment in full of the Settlement Amount, HHS agrees to release and refrain from instituting, directing or maintaining any debarment action under 45 C.F.R. Part 76 and 48 C.F.R. Part 9.4, or a fiscal disallowance action, against Johns Hopkins and the Released Entities and Individuals for the Covered Conduct. Nothing in this Paragraph precludes HHS from taking action against entities or persons, or for conduct and practices, for which civil, criminal or administrative claims have been reserved in Paragraph III.F. below. Furthermore, subject to the provisions of this paragraph, this Agreement does not affect or restrict the ability of HHS or any of its components, including the NIH Division of Grants Compliance and Oversight, to direct corrective actions or compliance activities to ensure future compliance with applicable statutes, regulations, OMB

Circulars, and official program and agency directives. Without waiving any of their legal rights, Johns Hopkins and the Released Entities and Individuals agree to work with HHS or any of its components to address any compliance issues in the event that they are identified.

F. 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 Johns Hopkins and the other Released Entities and Individuals) are any and all of the following:

1. Any civil, criminal or administrative claims arising under Title 26, U.S. Code (Internal Revenue Code);
2. Any criminal liability;
3. Except as explicitly stated in this Agreement, such as in Paragraph III.D. of this Agreement (pertaining to the release of certain specified claims by the United States) and Paragraph III.E. of this Agreement (pertaining to the release of certain specified claims by HHS), any other administrative liability, including mandatory and permissive exclusion from any federal health care programs;
4. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
5. Any liability based upon such obligations as are created by this Agreement;

6. Except as explicitly stated in this Agreement, any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services, provided by Johns Hopkins;

7. Except as explicitly stated in this Agreement, any liability for failure to deliver goods or services due; and

8. Any civil or administrative liability of individuals (including current or former physician and non-physician employees, trustees, officers and agents of Johns Hopkins) who are convicted, or who enter into a plea agreement related to the Covered Conduct.

Provided, however, that nothing in this Paragraph shall limit or apply to the releases provided in Paragraphs III.H. and III.I. below by the Relator, as that term is defined in the aforementioned Paragraphs III.H. and III.I.

G. In the event of any criminal prosecution or administrative action relating to the Covered Conduct, Johns Hopkins waives and will not assert any defenses that Johns Hopkins may have based on the 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 Settlement bars a remedy sought in such criminal prosecution or administrative action. Johns Hopkins agrees that this settlement is not punitive in purpose or effect for purposes of

criminal prosecution or administrative action. 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.

H. In consideration of the obligations of Johns Hopkins set forth in this Agreement, the Relator, on behalf of herself, her heirs, successors, partners, employees, agents, attorneys, consultants and assigns, agrees to dismiss the Civil Action pursuant to Paragraph III.S. of this Agreement, exclusive of her claim for retaliation under 31 U.S.C § 3730(h), and covenants not to sue with respect to, and releases, acquits, waives and forever discharges Johns Hopkins and the Released Entities and Individuals from any and all rights, claims, expenses, debts, liabilities, demands, obligations, costs, damages, injuries, actions and causes of action of every nature, whether known or unknown, suspected or unsuspected, in law or in equity, related or unrelated to the Civil Action or the Covered Conduct, including those for attorney's fees, prior to the effective date of this Agreement, but excluding her claims pursuant to 31 U.S.C § 3730(h) which Relator expressly reserves.

I. In addition to the foregoing, the Relator, on behalf of herself, and her heirs, successors, partners, employees, agents, attorneys, consultants and assigns, will and hereby does absolutely

and forever release and discharge the United States, and its agencies, employees, servants and agents, from any claims arising from or relating to the Civil Action or the Covered Conduct, or pursuant to 31 U.S.C. § 3730 (d)(1), for a share of any recoveries relating to or arising out of the Civil Action or this Agreement other than as set forth in this Agreement.

J. Johns Hopkins and the Released Entities and Individuals fully and finally release the Relator, and her heirs, successors, partners, employees, agents, attorneys, consultants and assigns, and the United States, its agencies, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) which Johns Hopkins or the Released Entities and Individuals asserted, could have asserted, or may assert in the future against the Relator, or her heirs, successors, partners, employees, agents, attorneys, consultants and assigns, or the United States, its agencies, employees, servants, and agents, related to the Civil Action, the Covered Conduct, or the United States' or the Relator's investigation of the Civil Action or Covered Conduct.

K. Johns Hopkins agrees to the following:

1. Unallowable Costs Defined: that all costs that would be unallowable under applicable cost principles and other regulations and official program directives applicable to government grants, contracts and cooperative agreements, including

but not limited to those contained in the Federal Acquisition Regulations (FAR), 45 C.F.R. Parts 74 and 92, and OMB Circular A-21, that are incurred by or on behalf of Johns Hopkins or any of the other released Entities or Individuals in connection with:

(a) the matters covered by this Agreement,

(b) the Government's audit(s) and civil investigation(s) of the matters covered by this Agreement,

(c) Johns Hopkins's or other Released Entities' or Individuals' investigation, defense, and compliance or other corrective actions undertaken in response to the Government's audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorney's fees),

(d) the negotiation and performance of this Agreement, and

(e) the payments made pursuant or ancillary to this Agreement, including any costs and attorneys' fees, are unallowable costs on Government grants, contracts, or cooperative agreements, and under the Medicare Program, Medicaid Program, TRICARE Program, Veterans Affairs Program (VA) and FEHBP. (All costs described or set forth in this Paragraph K.1. are hereafter, "unallowable costs").

2. Future Treatment of Unallowable Costs: These unallowable costs will be separately determined and accounted for in non-reimbursable cost centers by Johns Hopkins, and Johns Hopkins will not charge such unallowable costs directly or indirectly to any grants, contracts or cooperative agreements with

the United States or any State Medicaid Program, or seek payment for such unallowable costs through any cost report, cost statement, information statement, grant application, draw downs of grant funds, or other payment request submitted by Johns Hopkins or any of the other Released Entities or Individuals to any Government agency, including but not limited to NIH, or to the Medicare, Medicaid, TRICARE, VA or FEHBP programs (collectively referred to in this Agreement, as "the federal health care programs").

3. Treatment of Unallowable Costs Previously Submitted for Payment: Johns Hopkins further agrees that within 90 days of the effective date of this Agreement it will identify to any applicable agency of the United States Government and to all applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid, VA and FEHBP fiscal agents, any unallowable costs (as defined in this Paragraph) included in payments previously sought from the NIH or any other agency or contractor of the United States, or any State Medicaid Program, including, but not limited to, payments sought in connection with any grant (or grant application), contract, cooperative agreement, draw downs of grant funds, payments sought in any cost report, cost statements, information reports, or payment requests already submitted by Johns Hopkins or any of the other Released Entities or Individuals, and will request, and agree, that such cost reports, cost statements, information reports, grant applications, grant

award draw downs, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Johns Hopkins agrees that the United States, at a minimum, will be entitled to recoup from Johns Hopkins 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, grant applications, grant award draw downs, or requests for payment. If Johns Hopkins fails to identify such costs in past filed cost reports, grant applications, or payment requests in conformity with this Paragraph, the United States may seek an appropriate penalty or other sanction in addition to the recouped amount.

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 Johns Hopkins or any other of the Released Entities and Individuals on the effect of inclusion of unallowable costs (as defined in this Paragraph) on the cost reports, cost statements, information reports, grant applications, draw downs of grant funds, or payment requests of Johns Hopkins or any of the other Released Entities or Individuals. 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.

L. This Agreement is intended to be for the benefit of the Parties, only, including the United States and its agencies, employees, servants and agents, Johns Hopkins and the other Released Entities and Individuals, and the Relator and other individuals and entities released pursuant to Paragraphs III.D. and E., and H. through J. By this instrument, the Parties do not release any claims against any other person or entity, except to the extent specifically provided for in this Agreement.

M. Except as provided expressly herein, each party to this Agreement will bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

N. Johns Hopkins and the Relator represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

O. Pursuant to 31 U.S.C. § 3730(c)(2)(B), the Relator asserts that the settlement of the allegations as to the Civil Action is fair, adequate and reasonable under all the circumstances; will not challenge the Agreement; and expressly waives the opportunity for a hearing on any such objection.

P. 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 will be the United States District Court for the

District of Maryland. This paragraph will not apply, however, to any future agreements between Johns Hopkins and HHS or any of its components, including agreements that address corrective actions or compliance issues.

Q. Upon payment of the Settlement Amount and statutory attorneys' fees set forth in Paragraph III.C., or earlier if they so desire, the United States and the Relator shall promptly sign and file a Joint Stipulation of Dismissal in the Civil Action dismissing all counts other than Relator's claims for retaliation damages pursuant to 31 U.S.C § 3730(h) which Relator expressly reserves. The Joint Stipulation shall be with prejudice, except as to the United States acting on its own behalf with regard to the allegations of the Civil Action insofar as they do not encompass the Covered Conduct as to the Grants at Issue. The United States and the Relator shall take all reasonable steps to ensure said order of dismissal is entered.

R. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties. This Agreement is binding on all successors, transferees and assigns of Johns Hopkins and the Relator.

S. The individuals signing this Agreement on behalf of Johns Hopkins warrant that they are authorized by those parties to execute this Agreement. The individuals signing this Agreement on

behalf of Relator warrant that they are authorized by her 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.

T. The Relator warrants and represents that she has not heretofore assigned or transferred or purported to assign or transfer to any third party any claim released hereunder. The Relator shall indemnify and hold harmless Johns Hopkins, together with any of the other Released Entities and Individuals, from any and all claims, demands, or liabilities, including attorneys' fees, resulting from the breach of this warranty and representation.

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

V. This Agreement is effective on the date of signature of the last signatory to the Agreement. Facsimiles of signature shall constitute acceptable, binding signatures for purposes of this Agreement.

W. The Relator and Johns Hopkins consent to the United States' disclosure of this Settlement Agreement to the Public.

X. Any notices required under this Agreement shall be directed to the following persons:

On behalf of Johns Hopkins University:

Frederick G. Savage (or his successor)  
Deputy General Counsel

The Johns Hopkins University  
113 Garland Hall  
3400 North Charles Street  
Baltimore, Maryland 21218

On behalf of Johns Hopkins Bayview Medical Center:  
Joanne Pollak (or her successor)  
Vice President and General Counsel  
Johns Hopkins Health System Corporation  
600 North Wolfe Street  
Baltimore, Maryland 21287

On behalf of the United States, its agencies, departments and  
divisions:

Thomas M. DiBiagio (or his successor)  
United States Attorney  
101 W. Lombard Street  
Baltimore, Maryland 21201

On behalf of the Relator:

Robin Page West  
Cohan & West, P.C.  
201 North Charles Street  
Suite 2404  
Baltimore, Maryland 21201.

THE UNITED STATES OF AMERICA

THOMAS M. DIBIAGIO  
United States Attorney

By: \_\_\_\_\_  
Roann Nichols  
Assistant U. S. Attorney

Dated: \_\_\_\_\_

\_\_\_\_\_  
LARRY J. GOLDBERG  
Assistant Inspector General  
for Legal Affairs  
Office of Inspector General  
U.S. Department of Health and  
Human Services

Dated: \_\_\_\_\_

\_\_\_\_\_  
MARC WEISMAN  
Acting Director  
Office of Acquisition  
Management and Policy  
U.S. Department of Health and  
Human Services

Dated: \_\_\_\_\_

JOHNS HOPKINS UNIVERSITY

\_\_\_\_\_  
FREDERICK G. SAVAGE  
Deputy General Counsel  
Johns Hopkins University

Dated: \_\_\_\_\_

JOHNS HOPKINS BAYVIEW MEDICAL CENTER

\_\_\_\_\_  
JOANNE POLLAK  
Vice President and General  
Counsel  
Johns Hopkins Health System Corporation

Dated: \_\_\_\_\_

\_\_\_\_\_  
STEPHEN J. IMMELT  
Hogan & Hartson, L.L.P.  
111 South Calvert Street  
Suite 1600  
Baltimore, Maryland 21202

Dated: \_\_\_\_\_

Counsel for Johns Hopkins University  
and Johns Hopkins Bayview Medical  
Center

THE RELATOR

\_\_\_\_\_  
FAYE GRAU  
Relator

Dated: \_\_\_\_\_

\_\_\_\_\_  
ROBIN PAGE WEST  
Cohan & West. P.C.  
201 North Charles Street  
Suite 2404  
Baltimore, Maryland 21201

Dated: \_\_\_\_\_

Counsel for Relator