CERTIFICATION OF COMPLIANCE AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND RUSH UNIVERSITY MEDICAL CENTER

I. PREAMBLE

Rush University Medical Center (RUMC) hereby enters into this Certification of Compliance Agreement (CCA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS). Contemporaneously with this CCA, RUMC is entering into a Settlement Agreement with the United States, and this CCA is incorporated by reference into the Settlement Agreement.

The effective date of this CCA shall be the date on which the final signatory of this CCA executes this CCA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

II. INTEGRITY REQUIREMENTS

RUMC shall, for a period of three years from the Effective Date of this CCA:

A. Continued Implementation of Compliance Program. RUMC shall continue to implement its Compliance Program, as described in the attached Declaration (which is incorporated by reference as Appendix A), and continue to provide, at a minimum, the same approximate level of resources currently provided, throughout this time period. RUMC may amend its Compliance Program as it deems necessary, so long as those amendments are consistent with the overall objective of ensuring compliance with the requirements of Medicare, Medicaid, and all other Federal health care programs, as defined in 42 U.S.C. § 1320a-7b(f). RUMC's Compliance Program applies to all RUMC trustees, officers, employees, medical staff members, and persons who meet the definition of "workforce" under 45 CFR 160.103 (hereinafter, "Covered Persons"). Relevant contractors are required to agree to abide by the policies and procedures of RUMC's Compliance Program when performing services for RUMC.

B. Reporting of Overpayments. RUMC shall promptly refund to the appropriate Federal health care program payor any identified Overpayment(s). For purposes of this CCA, an "Overpayment" shall mean the amount of money RUMC has received in excess of the amount due and payable under any Federal health care program requirements. If, at any time, RUMC identifies or learns of any Overpayment, RUMC shall notify the

payor (e.g., Medicare fiscal intermediary or carrier) within 30 calendar days after identification of the Overpayment and take remedial steps within 60 calendar days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 calendar days after identification of the Overpayment, RUMC shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 calendar days after identification, RUMC shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies and, for Medicare contractors, shall include the information contained on the Overpayment Refund Form, provided as Appendix B to this CCA. Notwithstanding the above, notification and repayment of any Overpayment amount that is routinely reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

C. Reportable Events. RUMC shall report to OIG in writing within 30 calendar days after making a determination (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) that there is a Reportable Event, which shall mean anything that involves: (1) a substantial Overpayment, or (2) a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized. In such report, RUMC shall include the following information:

1. If the Reportable Event results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section II.B, and shall include all of the information on the Overpayment Refund Form, as well as:

    a. the payor's name, address, and contact person to whom the Overpayment refund was sent; and

    b. the date of the check and identification number (or electronic transaction number) by which the Overpayment was repaid/refunded;

2. a detailed description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

3. the date that RUMC, after reasonable opportunity for review or

investigation, determined that a Reportable Event occurred;

4. a description of RUMC's actions taken to correct the Reportable Event; and

5. any further steps RUMC plans to take to address the Reportable Event and prevent it from recurring.

D. Notification of Government Investigation or Legal Proceedings. Within 30 calendar days after discovery, RUMC shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to RUMC conducted or brought by a governmental entity or its agents involving an allegation that RUMC has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. RUMC shall also provide written notice to OIG within 30 calendar days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

E. Annual Reporting Requirements. RUMC shall submit to OIG annually a report that sets forth the following information for each Reporting Period (Annual Report):

1. A description of any material amendments to its Compliance Program and the reasons for such changes (a "material amendment" shall include the adoption of new or revised compliance policies and procedures);

2. Any changes to the level of resources dedicated to its Compliance Program and the reasons for such changes;

3. A summary of all internal or external reviews, audits, or analyses related to clinical trial billing (including, at a minimum, the objective of the review, audit, or analysis; the protocol or methodology for the review, audit, or analysis; and the results of the review, audit, or analysis) and any corrective action plans developed in response to such reviews, audits, or analyses;

4. A report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled

or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report; and

5. A report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report; and

6. A certification by the Chief Compliance Officer that: (a) to the best of his or her knowledge, except as otherwise described in the Annual Report, RUMC is in compliance with the requirements of this Section II; and (b) he or she has reviewed the Annual Report and has made reasonable inquiry regarding its content and believes that the information in the Annual Report is accurate and truthful.

The first Annual Report shall be received by OIG no later than 60 calendar days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

F. Notifications and Submission of Annual Reports. Unless otherwise specified in writing after the Effective Date, all notifications and Annual Reports required under this CCA shall be submitted to the following addresses:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202-619-2078
Facsimile: 202-205-0604

RUMC:

Chief Compliance Officer
Office of Corporate Compliance

Rush University Medical Center
707 S. Wood St., #317
Chicago, IL 60612
Telephone: 312-942-5303
Facsimile: 312-942-6875

Unless otherwise specified, all notifications and reports required by this CCA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such report or notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

G. OIG Inspection, Audit, and Review Rights. In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of RUMC's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of RUMC's locations for the purpose of verifying and evaluating: (a) RUMC's compliance with the terms of this CCA; and (b) RUMC's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by RUMC to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of RUMC's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. RUMC shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. RUMC's employees may elect to be interviewed with or without a representative of RUMC present.

H. Document and Record Retention. RUMC shall maintain for inspection all documents and records relating to clinical trial billing to the Federal health care programs, or to compliance with this CCA, for four years (or longer if otherwise required by law).

III. BREACH AND DEFAULT PROVISIONS

RUMC is expected to fully and timely comply with all of the Integrity Requirements set forth in this CCA.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, RUMC and OIG hereby agree that failure to comply with the Integrity Requirements set forth in this CCA may lead to the imposition of the following

monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day RUMC fails to establish and implement any of the following Compliance Program elements as described in Section II and the Declaration attached to this CCA as Appendix A:

a. a Chief Compliance Officer;

b. a Compliance Committee;

c. written Compliance Policies and Procedures (which shall also contain the equivalent of a compliance code of conduct);

d. the annual training of Covered Persons (however, for trustees, RUMC shall provide compliance training to the members of the Executive Committee and the Audit Committee of the Board of Trustees);

e. a compliance audit office that performs periodic reviews to monitor RUMC's compliance with Federal health care program requirements;

f. a Disclosure Program;

g. Ineligible Persons screening and removal requirements; and

h. notification to the OIG of government investigations and legal proceedings as set forth in Section II.D.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day RUMC fails to submit the Annual Reports to OIG in accordance with the requirements of Section II.E by the stated deadlines for submission.

3. A Stipulated Penalty of $1,500 for each day RUMC fails to grant access to the information or documentation as required in Section II.G of this CCA. (This Stipulated Penalty shall begin to accrue on the date RUMC fails to grant access.)

4. A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of RUMC as part of its Annual Reports or otherwise required by this CCA.

5. A Stipulated Penalty of $1,000 for each day RUMC fails to comply fully and adequately with any Integrity Requirements of this CCA. OIG shall provide notice to RUMC, stating the specific grounds for its determination that RUMC has failed to comply fully and adequately with the Integrity Requirement(s) at issue and steps RUMC shall take to comply with the Integrity Requirements of this CCA. (This Stipulated Penalty shall begin to accrue 10 calendar days after RUMC receives notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-4 of this Section III.A.

B. Timely Written Requests for Extensions. RUMC may, in advance of any due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CCA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after RUMC fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after RUMC receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that RUMC has failed to comply with any of the obligations described in Section III.A and after determining that Stipulated Penalties are appropriate, OIG shall notify RUMC of: (a) RUMC's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 calendar days after the receipt of the Demand Letter, RUMC shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section III.E. In the event RUMC elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until RUMC cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be

considered a material breach of this CCA and shall be grounds for exclusion under Section III.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section II.F.

4. *Independence from Material Breach Determination.* Except as set forth in Section III.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that RUMC has materially breached this CCA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section III.D, below.

D. Exclusion for Material Breach of this CCA.

1. *Definition of Material Breach.* A material breach of this CCA means:

a. a failure by RUMC to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section II.C;

b. a repeated or flagrant violation of the obligations under this CCA, including, but not limited to, the obligations addressed in Section III.A; or

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section III.C.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CCA by RUMC constitutes an independent basis for RUMC's exclusion from participation in the Federal health care programs. Upon a determination by OIG that RUMC has materially breached this CCA and that exclusion is the appropriate remedy, OIG shall notify RUMC of: (a) RUMC's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* RUMC shall have 30 calendar days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. RUMC is in compliance with the requirements of the CCA cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) RUMC has begun to take action to cure the material breach; (ii) RUMC is pursuing such action with due diligence; and (iii) RUMC has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter*. If, at the conclusion of the 30-day period, RUMC fails to satisfy the requirements of Section III.D.3, OIG may exclude RUMC from participation in the Federal health care programs. OIG shall notify RUMC in writing of its determination to exclude RUMC (this letter shall be referred to as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section III.E, below, the exclusion shall go into effect 30 calendar days after the date of RUMC's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, RUMC may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution.

1. *Review Rights*. Upon OIG's delivery to RUMC of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CCA, RUMC shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. §1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CCA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 calendar days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 calendar days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review*. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CCA shall be: (a) whether RUMC was in full and timely compliance with the requirements of this CCA for which OIG demands payment; and (b) the period of noncompliance. RUMC shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to

Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CCA and orders RUMC to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 calendar days after the ALJ issues such a decision unless RUMC requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 calendar days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CCA shall be:

a. whether RUMC was in material breach of this CCA;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) RUMC had begun to take action to cure the material breach within that period; (ii) RUMC has pursued and is pursuing such action with due diligence; and (iii) RUMC provided to OIG within that period a reasonable timetable for curing the material breach and RUMC has followed the timetable.

For purposes of the exclusion described herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for RUMC, only after a DAB decision in favor of OIG. RUMC's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude RUMC upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 calendar days after the ALJ issues such a decision, notwithstanding that RUMC may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 calendar days after the DAB decision. RUMC shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of RUMC, RUMC shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CCA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CCA.

IV. EFFECTIVE AND BINDING AGREEMENT

RUMC and OIG agree as follows:

A. This CCA shall be binding on the successors, assigns, and transferees of RUMC;

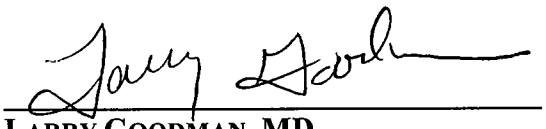
B. This CCA shall become final and binding on the date the final signature is obtained on the CCA;

C. Any modifications to this CCA shall be made with the prior written consent of the parties to this CCA;

D. OIG may agree to a suspension of RUMC's obligations under this CCA in the event of RUMC's cessation of participation in Federal health care programs. If RUMC withdraws from participation in Federal health care programs and is relieved of its CCA obligations by OIG, RUMC shall notify OIG at least 30 calendar days in advance of RUMC's intent to reapply as a participating provider or supplier with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the CCA should be reactivated or modified.

E. The undersigned RUMC signatories represent and warrant that they are authorized to execute this CCA. The undersigned OIG signatory represents that he is signing this CCA in his official capacity and that he is authorized to execute this CCA.

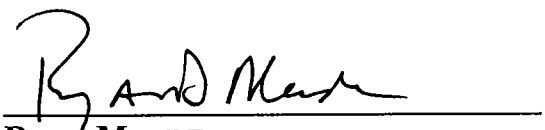
ON BEHALF OF RUMC



12-2-05

LARRY GOODMAN, MD
PRESIDENT & CEO
RUSH UNIVERSITY MEDICAL CENTER

DATE



12-2-05

RYAN MEADE
COUNSEL FOR
RUSH UNIVERSITY MEDICAL CENTER

DATE

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

_____ _____
LEWIS MORRIS **DATE**
Chief Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

Appendix B

OVERPAYMENT REFUND FORM

TO BE COMPLETED BY MEDICARE CONTRACTOR

Date:
Contractor Deposit Control #_____ Date of Deposit: _____
Contractor Contact Name:_____ Phone #_____
Contractor Address:_____
Contractor Fax:

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.

PROVIDER/PHYSICIAN/SUPPLIERNAME_____
ADDRESS
PROVIDER/PHYSICIAN/SUPPLIER #_____CHECK NUMBER#_____
CONTACT PERSON:_____PHONE #_____
AMOUNT OF CHECK $_____ CHECK DATE_____

REFUND INFORMATION

For each Claim, provide the following:
Patient Name_____HIC #_____
Medicare Claim Number_____Claim Amount Refunded $_____
Reason Code for Claim Adjustment:_____ (Select reason code from list below. Use one reason per claim)

(Please list all claim numbers involved. Attach separate sheet, if necessary)

*Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling, please indicate methodology and formula used to determine amount and reason for overpayment:*_____

For Institutional Facilities Only:
Cost Report Year(s) _____
(If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)

For OIG Reporting Requirements:
Do you have a Corporate Integrity Agreement with OIG? Yes No

Reason Codes:

Billing/Clerical Error	MSP/Other Payer Involvement	Miscellaneous
01 - Corrected Date of Service	08 - MSP Group Health Plan Insurance	13 - Insufficient Documentation
02 - Duplicate	09 - MSP No Fault Insurance	14 - Patient Enrolled in an HMO
03 - Corrected CPT Code	10 - MSP Liability Insurance	15 - Services Not Rendered
04 - Not Our Patient(s)	11 - MSP, Workers Comp.(Including Black Lung	16 - Medical Necessity
05 - Modifier Added/Removed	12 - Veterans Administration	17 - Other (Please Specify)
06 - Billed in Error		_____
07 - Corrected CPT Code		