

10849

OMB No. 0990-0278

Approved for use through 1/31/2008

**U.S. Department of Health and Human Services (DHHS)
Federalwide Assurance (FWA) for the Protection of Human Subjects
For Domestic (U.S.) Institutions**

1. Institution Filing Assurance

Legal Name: COLUMBIA UNIVERSITY MEDICAL CENTER

City: NEW YORK

State: NY

DHHS Institutional Profile Code:

Federal Entity Identification Number (EIN):

This Assurance replaces:

2. Institutional Components

List below all components over which the Institution has legal authority that operate under a different name. Also list with an asterisk (*) any alternate names under which the Institution operates. The Institution should have available for review by the Office for Human Research Protections (OHRP) upon request a brief description and line diagram explaining the interrelationships among the Assurance Signatory Official, the Institutional Review Board (IRB), IRB support staff, and investigators in these various components.

NOTE: The Signatory Official signing this Assurance must be legally authorized to represent the Institution providing this Assurance and all components listed below. Entities that the Signatory Official is not legally authorized to represent may not be listed here without the prior approval of OHRP.

| Name of Component or Alternate Names Used | City, State (or Country if Outside U.S.) |
|-------------------------------------------|------------------------------------------|
| COLL PHYSICIANS AND SURGEONS | NEW YORK CITY, NY |
| MAILMAN SCH PUBLIC HLTH | NEW YORK CITY, NY |

3. Statement of Principles

This Institution assures that all of its activities related to human subjects research, regardless of funding source, will be guided by the ethical principles in the following documents:

THE BELMONT REPORT

4. Applicability:

(a) This Institution assures that whenever it engages in human subjects research conducted or supported by any federal department or agency that has adopted the Federal Policy for the Protection of Human Subjects, known as the Common Rule, the Institution will comply with the Terms of the Federalwide Assurance for Institutions Within the United States (contained in a separate document on the OHRP website), unless the research is otherwise exempt from the requirements of the Common Rule or a department or agency conducting or supporting the research has determined that the research shall be covered by a separate assurance.

(b) Optional: This Institution elects to apply the following to all of its human subjects research regardless of the source of support, except for research that is covered by a separate assurance:

The Common Rule and subparts B, C, and D of the HHS regulations at 45 CFR part 46

5. Designation of Institutional Review Boards (IRBs)

This Institution designates the following IRB(s) for review of research under this Assurance (if the IRB has not previously registered with HHS or has not provided a membership roster to HHS, please submit to OHRP the appropriate IRB registration materials which are available on the OHRP website).

NOTE: Reliance on the IRB of another institution or organization or an independent IRB must be documented by a written agreement that is available for review by OHRP upon request. OHRP's sample IRB Authorization Agreement may be used for this purpose, or the parties involved may develop their own agreement. Future designation of other IRBs requires an update of the FWA.

| HHS IRB Registration Number | Name of IRB As Registered with HHS |
|-----------------------------|---------------------------------------------------|
| IRB00000080 | BIOMEDICAL RSCH ALLIANCE NEW YORK (BRANY) IRB A |
| IRB00000461 | COLUMBIA U MED CTR IRB #1 |
| IRB00000488 | RSCH FDN MENTAL HLTH IRB #1 |
| IRB00000533 | WESTERN IRB #1-8 & #11-12 |
| IRB00000781 | NATIONAL CANCER INST CENTRAL IRB #1 (ADULT) |
| IRB00000952 | JOAN & SANFORD I. WEILL MED COLL CORNELL U IRB #1 |
| IRB00002973 | COLUMBIA U MED CTR IRB #2 |
| IRB00003506 | COLUMBIA U MED CTR IRB #3 |
| IRB00004327 | JOAN & SANFORD I WEILL MED COLL CORNELL U IRB #2 |

6. Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person)

First Name: GEORGE

Middle Initial: C

Last Name: GASPARIS

Degrees or Suffix (e.g., MD, PhD):

Institutional Title: EXECUTIVE DIRECTOR, HUMAN SUBJECTS PROTECTION I

Institution: COLUMBIA UNIVERSITY MEDICAL CENTER

Telephone: (212) 305-3257

FAX: (212) 305-1316

E-mail: GG2120@COLUMBIA.EDU

Address: COLUMBIA UNIVERSITY MEDICAL CENTER

722 WEST 168TH ST, 4TH FLOOR

City: NEW YORK

State: NY

Zip Code: 10032

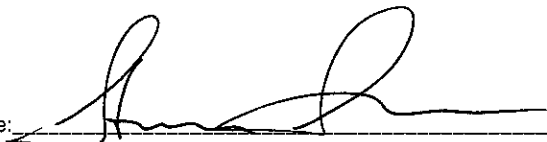
NOTE: Institutions operated by the U.S. Government may need to obtain department or agency clearance prior to submission of the FWA to OHRP. Please contact the relevant department or agency Human Subject Protections Officer before forwarding this Assurance to OHRP.

7. Signatory Official (i.e., Official Legally Authorized to Represent the Institution
-- cannot be IRB Chairperson or IRB member)

I understand that the Assurance Training Modules on the OHRP website describe the responsibilities of the Signatory Official, the IRB Chair(s), and the Human Protections Administrator under this Assurance. Additionally, I recognize that providing research investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education about human subject protections will help ensure that the requirements of this Assurance are satisfied.

Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure protections for human subjects as specified above. The IRB(s) designated above are to provide review for all research to which this Assurance applies. The designated IRB(s) will comply with the Terms of the Federalwide Assurance for Institutions Within the United States and possess appropriate knowledge of the local context in which this Institution's research will be conducted.

All information provided with this Assurance is up-to-date and accurate. I am aware that false statements could be cause for invalidating this Assurance and may lead to other administrative or legal action.

Signature:  Date: 7/7/05
Steven Shea

First Name: STEVEN Middle Initial: Last Name: SHEA
Degrees or Suffix (e.g., MD, PhD): MD Institutional Title: SENIOR ASSOCIATE DEAN FOR CLINICAL AFFAIRS
Institution: COLUMBIA UNIVERSITY MEDICAL CENTER
Telephone: (212) 342-2214 FAX: (212) 305-6993 E-mail: SS35@COLUMBIA.EDU
Address: COLUMBIA UNIVERSITY HEALTH SCIENCES
VP & DEAN'S OFFICE, 630 W. 168TH ST.
City: NEW YORK State: NY Zip Code: 10032

Submission Number: 10849

7/6/2005 4:00:16 PM

Submitting Institution: COLUMBIA UNIVERSITY MEDICAL CENTER
NEW YORK, NY

OMB No. 0990-0278

Approved for use through 1/31/2008

8. FWA Approval

The Federalwide Assurance for the Protection of Human Subjects for Institutions Within the United States submitted to HHS by the above Institution is hereby approved.

Assurance Number:

Expiration Date:

Signature of HHS Approving Official: _____ Date: _____

Public burden for this collection of information is estimated to average two hours for a new FWA filing and less than an hour for an FWA renewal or update. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: OS Reports Clearance Officer, Room 503, 200 Independence Avenue, SW., Washington, DC 20201. Do not return the completed form to this address.

Subject: Electronic Update/Renewal of FWA00002636 Approved by OHRP

From: <OHRPElectronicSubmissionSystem@mail.nih.gov>

Date: Mon, 8 Aug 2005 15:32:18 -0400

To: <at2059@columbia.edu>, <ss35@columbia.edu>, <gg2120@columbia.edu>, <dchu@osophs.dhhs.gov>

PLEASE DO NOT RESPOND TO THIS COMMUNICATION

This is an e-mail from the Office for Human Research Protections (OHRP) that was generated automatically with the approval of your institution's electronic submission of an update/renewal to your Federalwide Assurance (FWA). You are receiving this e-mail because you are the Signatory Official and/or Human Protections Administrator on the FWA, or you are the person that submitted the electronic document to OHRP.

The number previously assigned to your institution's FWA is FWA00002636

Whenever there is a change in the information provided to OHRP under your institution's FWA, you must submit an update/renewal. You may do this electronically by going to the OHRP Electronic Submission System at <http://ohrp.cit.nih.gov/efile>. Your FWA must be renewed at least every 3 years.

You will find this approval listed on our website at <http://ohrp.cit.nih.gov/search/asearch.asp#ASUR>.

Sincerely,

Division of Policy and Assurances
Office for Human Research Protections
U.S. Department of Health and Human Services
1101 Wootton Parkway, Suite 200
Rockville, MD 20852