

FWA #: FWA00002636

OMB No. 0990-0278

Institution: The Trustees of Columbia University in the City of New York on behalf of the
Columbia University Irving Medical Center

Approved for use through August 31, 2023

Expires: 12/29/2027

Federalwide Assurance (FWA) for the Protection of Human Subjects

1. Institution Filing Assurance

Legal Name: The Trustees of Columbia University in the City of New York on behalf of the Columbia
University Irving Medical Center

City: New York

State/Province: NY

Country: USA

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.

NOTE: The Signatory Official signing this Assurance must be legally authorized to represent the Institution providing this Assurance and all components listed below.

Name of Component or Alternate Names Used	City	State (or Country if Outside U.S.)	
Coll Physicians and Surgeons	NEW YORK CITY	NY	A
Mailman School of Public Health	New York	NY	A
College of Dental Medicine	New York	NY	A
School of Nursing	New York	NY	A

3. Statement of Principles

This Institution assures that all of its activities related to human subjects research, regardless of the source of support, will be guided by the following statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution. (indicate below)

The Belmont Report

4. Applicability

(a) This Assurance applies whenever this Institution becomes engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule), unless the research is otherwise exempt from the requirements of the Common Rule or the department or agency conducting or supporting the research determines that the research shall be conducted under 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. Assurance of Compliance with the Terms of the Federalwide Assurance

(a) This Institution assures that whenever it engages in research to which this Assurance applies, it will comply with the Terms of the Federalwide Assurance (contained in a separate document on the Office for Human Research Protections (OHRP) website).

8. Signatory Official (i.e., Official Legally Authorized to Represent the Institution)

I have read and agree to the Terms of the Federalwide Assurance.

I recognize that providing research investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education and training 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) that this institution relies upon will comply with the Terms of the Federalwide Assurance when reviewing research covered by this Assurance 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: Andrew B Lassman M.D.

Date: 12/28/2022

First Name: Andrew Middle Initial: B Last Name: Lassman

Degrees or Suffix: M.D. Institutional Title: Associate Dean of Clinical Research Compliance at VP&S

Institution: Columbia University Medical Center

Telephone: 212 342-0871 FAX: 212 342-1246 E-Mail: abl7@columbia.edu

Address: The Neurological Institute, 710 West 168th Street

City: New York State/Province: NY Country: USA

9. FWA Approval

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

Assurance Number: FWA00002636

Expiration Date: 12/29/2027

Signature of HHS Approving Official: Cecilia Chirinos

Date: 12/29/2022

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0990-0278 . The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: U.S. Department of Health & Human Services, OS/OCIO/PRA, 200 Independence Ave., S.W., Suite 336-E, Washington D.C. 20201, Attention: PRA Reports Clearance