

FWA #: FWA00003831
Institution: Trustees of Columbia University in the City of New York (The)
Expires: 01/20/2028

OMB No. 0990-0278
Approved for use through August 31, 2023

Federalwide Assurance (FWA) for the Protection of Human Subjects

1. Institution Filing Assurance

Legal Name: Trustees of Columbia University in the City of New York (The)
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.)	
Lamont-Doherty Earth Observatory	New York	NY	A
Earth Institute	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).

6. Designation of Institutional Review Boards (IRBs)

This Institution assures that it will rely upon only IRBs registered with OHRP for review of research to which this FWA applies. This institution (a) designates the following internal IRB(s) for review of research under this Assurance; or (b) does not have an internal IRB and designates the following external IRB for review of all research to which this FWA applies or, if multiple external IRBs are relied upon, the following external IRB that reviews the largest percentage of research to which this FWA applies.

NOTE: Institutions designating internal IRBs do not need to designate any of the external IRBs upon which it relies.

HHS IRB Registration Number	Name of IRB as Registered with HHS	Is the IRB Internal or External to the Institution?
IRB00000461	Columbia U, CUMC IRB #1	I
IRB00002973	Columbia U, CUMC IRB #2	I
IRB00003506	Columbia U, CUMC IRB #3	I
IRB00006799	Columbia U, Morningside IRB	I
IRB00006882	Columbia U, CUMC IRB #4	I
IRB00008612	Columbia U IRB #6	I
IRB00010414	Columbia University IRB #7	I

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

First Name: Brenda Middle Initial: Last Name: Ruotolo
 Degrees or Suffix: Institutional Title: Associate Vice President for Human Research Protection
 Institution: Columbia University in the City of New York
 Telephone: 929 746-0534 FAX: 212 305-1316 E-Mail: blr2102@columbia.edu
 Address: Human Research Protection Office
 154 Haven Avenue, 2nd Floor
 City: New York State/Province: NY Country: USA

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: Jeannette Wing Ph.D.

Date: 01/20/2023

First Name: Jeannette Middle Initial: Last Name: Wing

Degrees or Suffix: Ph.D. Institutional Title: Executive Vice President for Research

Institution: Trustees of Columbia University in the City of New York (The)

Telephone: 212 854-1656 FAX: 212 854-1680 E-Mail: jw3585@columbia.edu

Address: 313 Low Memorial Library
535 W. 116th Street MC 4310

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: FWA00003831

Expiration Date: 01/20/2028

Signature of HHS Approving Official: Cecilia Chirinos

Date: 01/20/2023

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