Institutional Review Board

Primarily interested in human subjects research

Concerns ethical practice, safety and privacy

Federal and State Compliance

Requires Training
Columbia Undergraduates

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Barnard Undergraduates

Need to fill out the student form found at:

http://barnard.edu/sites/default/files/student_as_pi.pdf

on this website for students:

http://www.barnard.edu/provost/research-professional-development/irb

Send this to:
Lisa Son
Associate Professor
Ison@barnard.edu
About the Human Research Protection Program (HRPP) / Institutional Review Board (IRB)

Purpose / Scope / Responsibilities

Columbia University has implemented a comprehensive Human Research Protection Program (HRPP), which is under the leadership of the Executive Vice President for Research. The program is charged with the responsibility of ensuring that all human research studies conducted by Columbia faculty, employees, and staff are conducted ethically and in a manner that promotes the protection of participants in research. In accordance with institutional policy, all such research must not only be in compliance with state and federal regulations, but must also meet or exceed the standards of accreditation as set forth by the Association for Accreditation of Human Research Protection Programs (AAHRPP).

The Columbia HRPP is composed of all entities, offices, and individuals engaged in and/or responsible for the review and conduct of human research at Columbia University (CU), and New York Presbyterian Hospital (NYPH). CU has two Federalwide Assurances (FWAs): one for the main campus at Morningside and one for Columbia University Medical Center (CUMC). NYPH has its own FWA and is a separate legal entity from CU. Although these are three separate legal entities, one HRPP is responsible for all human research conducted at any of these three locations, or by their faculty, employees, or staff regardless of location.

For more information, follow this link to the Executive Summary of the Human Research Protection Program.

IRB Roster and Meeting Schedule

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Quality Improvement Program

The IRB conducts quality improvement initiatives to evaluate and strengthen the quality of our human research protection program. The primary purpose of these initiatives is to increase the efficiency of our performance and ensure compliance with federal regulations for the protection of human subjects in research.

Compliance Oversight
Required Training:

Human Subjects Protection

Columbia University Human Research Protection Program

Education & Training

CITI Requirement

Program Overview

Before a protocol will be approved by a CU IRB, the PI must review the Human Subjects Protection Training course and receive a passing score of 80 or greater on the relevant exams. Research personnel other than the PI who have contact with subjects, contact with confidential study data, or are otherwise engaged in the research (i.e., key personnel) must also complete training in the protection of human subjects prior to participation in the research.

Effective October 20, 2010, there is a requirement for refresher training to be completed every 3 years. In addition, all research personnel who have previously completed the CUMC Good Clinical Practices Courses or the Morningside Human Subjects Training Course must complete the CITI Human Subjects Protection Training Program no later than March 31, 2011.

For more information on the Human Subjects Protection training requirement, click see our FAQs.

https://www.rascal.columbia.edu/login/tc0087/
Columbia Human Subjects Protection Training Program

Human Subjects Protection Training Update: Requirement for Continuing Education

CITI Requirement

Program Overview

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https://www.rascal.columbia.edu/login/tc0087/

HIPAA Privacy Training

Key personnel who will be conducting research involving Protected Health Information (PHI) must also complete the online HIPAA (Health Insurance Portability and Accountability Act) training course prior to participation in the research.

https://www.rascal.columbia.edu/login/tc0019/

Research with Minors

If the study population includes children, completion of the CITI Biomedical Research with Minors module is required.

Additional Training Opportunities:

IRB-Investigator Meetings

The IRB-Investigator Meetings provide regular educational opportunities that address current human subjects protection topics.

http://www.columbia.edu/cu/irb/education/index.html#required_training
The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") provides comprehensive guidance for patients including their privacy rights concerning the use or disclosure of their medical information. These rights are described in detail in the Notice of Privacy Practices.

### Notice of Privacy Practices
- Notice of Privacy Practices (NPP)
- Notice of Privacy Practices (Spanish)
- Patient Acknowledgement Form
  - Patient Acknowledgement Form (Spanish)

### HIPAA Forms
- Authorization to Release Medical Information (Legal)
- Authorization to Release Medical Information (Legal) (Spanish)
- Business Associate Agreement
- Confidentiality Agreement
- HIPAA Fax cover sheet
- Important Information About Patient Email
- Patient Request for Email Communications

### HIPAA Home
Office of HIPAA Compliance
Columbia University Medical Center
630 West 168th Street, Box 159
New York, NY 10032
Tel: (212) 342-0059
Fax: (212) 342-5173
Karen Pagliaro-Meyer
Privacy Officer
kpagliaro@columbia.edu

Information Security Policies & Procedures
Policies & Procedures
Accounting for Disclosures
Authorization to Disclose Medical Information
Breach Notification
Business Associates
Email Policy
Fax

### HIPAA Training
All CUMC employees must complete mandatory HIPAA training. All staff receive HIPAA training during welcome program/orientation.

### HIPAA Education Material
- HIPAA & HITECH Briefing - Privacy and Information Security 2013
- HIPAA & HITECH Briefing Information Security and Privacy 2013 - Video (UNI required)
- HIPAA & HITECH Briefing - Information Security and Privacy 2012
- HIPAA & HITECH Briefing Information Security and Privacy 2012 - Video (UNI required)
- Welcome Program 2013
What Is RASCAL?
Who Can Use RASCAL?
What Can I Do With RASCAL?
Other Useful Information
Use this link to access all of your HIPAA Forms.

Note:
- Do not open more than one RASCAL browser window at the same time.
- Please disable any Pop-up Blockers and enable JavaScript & Cookies.
- This system will log you out after approximately one hour of inactivity. Please save your work often.
Useful Web Resources

http://www.columbia.edu/cu/irb/

http://www.cumc.columbia.edu/hipaa/

https://www.rascal.columbia.edu