

Columbia University
Human Research Protection Program
Executive Summary
December 20, 2017

I. Name:

- Name for posting on the AAHRPP website: Columbia University in the City of New York
- Components and Major Administrative Units:
 - Columbia University Morningside including:
 - Business School
 - Columbia College
 - Fu Foundation School of Engineering and Applied Science
 - Graduate School of Arts and Sciences
 - Journalism School
 - Law School
 - School of the Arts
 - School of General Studies
 - School of Professional Studies
 - School of Social Work
 - Columbia University Manhattanville
 - Lamont Doherty Earth Observatory
 - Columbia University Medical Center
 - College of Physicians & Surgeons
 - Mailman School of Public Health
 - College of Dental Medicine
 - School of Nursing

II. Overview and Purpose:

Columbia University (CU or Columbia) has developed and implemented a comprehensive Human Research Protection Program (HRPP; hereafter referred to as the Columbia HRPP) in accordance with the recommendations in the Institute of Medicine Report entitled Responsible Research: A Systems Approach to Protecting Research Participants (October 3, 2002). The program is charged with the responsibility of ensuring that all human subjects research conducted by Columbia faculty, employees, and staff is conducted ethically and in a manner that promotes the protection of human subjects in research. Protections for human participants in 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 covers all entities, offices, and individuals engaged in and/or responsible for the review, conduct and oversight of human research at Columbia, including the Columbia University Medical Center (CUMC), and NewYork-Presbyterian Hospital (NYP) on the CUMC campus and other designated components of NYP. CU has two Federalwide Assurances (FWAs): one for CUMC and one for the Morningside and Lamont campuses (CU-MS).

Research activities at Columbia's Manhattanville campus are conducted by researchers who are affiliated with a department or school at one of the other campuses; hence, the research is covered under the respective FWA. NYP is a separate legal entity from CU, and the NYP facilities for which Columbia provides IRB review each have their own FWA. The Columbia HRPP maintains five FWAs and is responsible for all human research conducted at CUMC, CU-MS and the afore-mentioned components of NYP, or by any affiliated faculty, employees, or staff of CU and NYP as applicable, regardless of location of the research.

III. Description:

G. Michael Purdy, Ph.D., Executive Vice President for Research (EVPR), is the institutional official with ultimate responsibility for Columbia's HRPP. The Executive Director (ED) of Columbia's Human Research Protection Office (HRPO) is the senior officer responsible for the day-to-day administrative and management oversight of the HRPP, and for the management of all Institutional Review Boards (IRBs) at CU. The ED reports to the EVPR, through Deborah Stiles, Chief Operating Officer for the Office of the Executive Vice President for Research and Vice President for Research Operations and Policy (VPRO) and maintains a close working relationship with Steven Shea, M.D., Senior Vice Dean, College of Physicians and Surgeons (P&S).

IV. Key representatives:

Organizational officials:

Brenda Ruotolo, Executive Director, HRPO
Alan Teller, Director, IRB Operations
Challace Pahlevan-Ibrekic, MS, Director, IRB Management
Thresiamma Lukose, Pharm.D., Director, Compliance Oversight
Laurence Butaud-Rebbaa, Assistant Director, IRB Management

Individuals to whom the Organizational officials report:

G. Michael Purdy, Ph.D., EVPR
Deborah Stiles, J.D., VPRO
Steven Shea, M.D., Senior Vice Dean, P&S (dotted line reporting relationship)

Individuals who provide legal counsel to the HRPO/IRBs:

Jane Booth, Esq., General Counsel
Associate General Counsels

IRB Chairs and Vice Chairs

CUMC IRB 1: Sudha Kashyap, M.D., Chair; Marilyn Morris, M.D., Vice Chair
CUMC IRB 2: Elaine Larson, Ph.D., Chair; Pietro Canetta, M.D., Vice Chair
CUMC IRB 3: Neil Schluger, M.D., Chair; Katherine Biagas, M.D., Vice Chair
CUMC IRB 4: Mark Heaney, M.D., Chair; Alice Lee, M.D., Vice Chair
CUMC IRB 5: Walter Palmas, M.D., Chair; Krystof Kiryluk, M.D., Vice Chair
CUMC IRB Exp: Sudha Kashyap, M.D. Elaine Larson, Ph.D.;
Neil Schluger, M.D.; Mark Heaney, M.D., Walter Palmas, M.D., Chairs
MS IRB: Andrew Nathan, Ph.D., Chair; Robert Downs, Ph.D., Vice Chair

HRPO Staff:

IRB 1: Diana Lesmes, Manager; Lisa Lotwin, IRB Specialist
IRB 2: Deirdre Lombardi, Manager; Erin Murphy, IRB Specialist
IRB 3: Yaritza Collazo, Manager; Stephanie Martinez, IRB Specialist
IRB 4: Laurence Butaud-Rebbaa, Interim Manager; Jianyuan Hua, Assistant Manager;
Qiana Quiles, IRB Specialist; Marriam Khan, IRB Specialist
IRB 5: Deirdre Lombardi, Manager; Brenna Posner, IRB Specialist
IRB Expedited Review: Rafael Santos, Senior Manager; Vanessa Moya, IRB Specialist;
Isabel Bustamante, IRB Specialist; Elizabeth Baez, IRB Specialist
IRB Morningside: Rafael Santos, Interim Manager; Annie Barry, Assistant Manager;
Compliance Oversight Team: Grace Kim, Research Compliance Auditor; Maryanne
McGinn, Research Compliance Auditor
Operations Team: Rui Ferreira, IRB Specialist; Rachel Yarmolinsky, IRB Regulatory
Specialist

Pharmacy Representatives responsible for control of investigational drugs:

Elnaz Anjom, Pharm.D., Director, Research Pharmacy
Karol Wollenburg, Pharm.D., Director, Drug Use Policy and Acquisition, NYP

Individuals who manage or chair the committee that manages financial interest of investigators:

Henry Spotnitz, M.D., Chair, Conflicts of Interest Committee
Naomi Schrag, J.D., VP for Research Compliance & Training

Individuals responsible for reviewing and signing grants and sponsor contracts:

Rudina Odeh-Ramadan, Pharm.D., Vice President, Research Administration
Helen Kim, Pharm.D., Executive Director, Clinical Trials Office

Key personnel for affiliated organizations:

Craig Albanese, M.D., Senior Vice President and Chief Operating Officer, NYP/Morgan
Stanley Children's Hospital and Sloane Hospital for Women (Institutional
Official on NYP FWA)
David Strauss, M.D., Director of Research Operations and Compliance New York State
Psychiatric Institute (NYSPI)

V. Types of human research conducted:

The Columbia research enterprise is extensive in its size and broad in its scope and nature of activities, including biomedical, behavioral, and epidemiological research, as well as studies in the area of health services. Subjects may include healthy volunteers, as well as patients and other individuals who may be considered vulnerable due to medical, cognitive, emotional, economical, educational, age or other factors. Although much of the research is conducted in the New York City area and on Columbia campuses, researchers also actively conduct research at other sites, both domestic and international. Furthermore, many Columbia researchers collaborate on projects with investigators at other institutions.

The Columbia HRPP includes approximately 3,500 faculty members and accounts for approximately 2,200 new human subjects research studies each year and manages approximately 6,000 studies that have been approved or determined to be exempt. Most of the human subjects research (approximately 75-80%) is conducted by CUMC on its campus. Approximately 12% of

research is conducted at CU-MS and the rest of the research portfolio (approximately 10-12%) is conducted off campus, including internationally. Funding sources, as expected, include both public (primarily HHS) and private support (primarily industry or foundation).

All research conducted by Columbia and all CU IRBs are governed by the principles of the Belmont Report and, as applicable, the federal regulations for the protection of human subjects in research as codified by: 1) the U.S. Department of Health and Human Services regulations, 45 CFR Part 46, Subparts A (Common Rule), B, C, and D; 2) the U.S. Food and Drug Administration (FDA) Regulations, 21 CFR Parts 50, 56, 312, 600, and 812; 3) other applicable federal regulations; 4) ICH-Good Clinical Practice (E6) to the extent it is consistent with FDA Regulations; 5) the Department of Education Family Education Rights and Privacy Act (FERPA); 6) New York State Public Health Law Article 24-A (2440-2446) (Protection of Human Subjects), Civil Rights Law Article 7, Section 79-1 (Confidentiality of Genetic Tests) and others, as applicable; 6) Columbia institutional policies; and 7) the AAHRPP Accreditation Standards.

VI. Other Organizations:

NYP is a separate legal entity whose activities at CUMC are a component of the Columbia HRPP. All policies and practices of the HRPP apply to research conducted at any of the NYP facilities for which Columbia provides IRB services, or elsewhere at CU.

VII. Institutional Culture

Essential to the success of the Columbia HRPP is the institutional culture or conscience that permeates all components of the program. Research is one of the key missions of Columbia, which prides itself on its commitment towards excellence in all research activities. Columbia and NYP recognize that the ethical conduct of research is not only vital for the success of the research enterprise and the public trust of surrounding communities in our research programs, but more importantly that the institutions have a moral responsibility to act accordingly. Towards these ends, the EVPR and other Institutional Officials of CU-MS, CUMC, and NYP lead the Columbia HRPP in many different ways, including: 1) instilling the above described culture; 2) supporting the Columbia HRPP with the necessary funds, resources, and intellectual support; and 3) providing the necessary authoritative leadership and support for ensuring the integrity of Columbia's program for the handling of alleged noncompliance incidents. A brief overview of the Columbia HRPP is provided below.

A. HRPO and IRBs

The mission of the CU HRPO and IRBs is to enhance and facilitate the ethical conduct of human subjects research conducted under the auspices of Columbia, and by Columbia researchers, regardless of location. The HRPO and IRBs will perform this mission through their review of human subjects research, their educational and training initiatives, and their compliance oversight and quality improvement programs.

1. HRPO

The HRPO is the central administrative office for the Columbia HRPP. This office serves as the central repository of all information affecting the protection of human subjects in research. An organizational chart of the HRPO is attached on page 8.

The HRPO is responsible for the management and oversight of all IRBs at CU-MS and CUMC, as well as the reporting of all safety and noncompliance issues regarding research involving human subjects. In addition, the HRPO is responsible for ensuring that all relevant information affecting the safety and welfare of human subjects in research is reported to the IRBs, and as appropriate to the Institutional Officials, federal regulatory agencies, sponsors, and AAHRPP. The HRPO has two locations, with offices at CUMC and CU-MS.

Four committees in the HRPO support initiatives to improve the ethical conduct and review of research: 1) Education and Training Committee, 2) Policy Committee, 3) Accreditation Committee, and 4) Rascal Committee. The purpose of each committee is described in more detail below.

2. Institutional Review Boards

There are seven IRBs in the Columbia HRPP. Six IRBs (five full-board, one expedited review) are responsible for review of human subjects research conducted by faculty, staff, and students at CUMC and NYP, and all FDA-regulated research, and one IRB is responsible for human research conducted by faculty, staff, and students at CU-MS. Additional IRBs may be added as necessary to ensure adequate and timely review of research proposals submitted for consideration.

The CU IRBs also serve as the reviewing IRB for certain multicenter studies conducted at non-Columbia sites, through the terms of IRB Authorization Agreements by which institutions cede responsibility for IRB review to Columbia.

3. External IRBs

CUMC and NYP have IRB Authorization Agreements with numerous other institutions, including academic medical centers and independent IRBs, through which responsibility for IRB review is ceded to a non-Columbia IRB. Agreements may be for one protocol or for multiple protocols that share defined characteristics. The process for entering into such agreements involves consideration of the status of the IRB that will conduct the review, e.g., whether it is accredited or can otherwise document good regulatory standing; the procedures by which reviews will be conducted and interactions between CUMC/NYP and the reviewing IRB will occur and be documented; proposed delineation of responsibility for HIPAA and conflict of interest matters; legal terms; and funding requirements. Columbia remains responsible for the conduct of the research in all cases, and may implement oversight procedures to supplement the oversight of the reviewing IRB. Examples of longstanding relationships include reliance on the IRBs of the following institutions: New York State Psychiatric Institute (NYSPI), Weill Cornell Medical Center of Cornell University, National Cancer Institute, Massachusetts General Hospital/Partners (central IRB for the NeuroNEXT trials), Fred Hutchinson Cancer Center (central IRB for certain HVTN studies), University of Cincinnati (central IRB for StrokeNet trials), as well as some other external IRBs that have been designated as the Single IRB (sIRB) for certain multicenter studies or consortia. The

NIH sIRB Policy that is effective in January 2018 for multicenter clinical trials funded by the National Institutes of Health will significantly increase the number of reliance agreements into which CUMC and NYP will enter.

4. Compliance Oversight Team

The Compliance Oversight Team (COT) is responsible for investigating and managing allegations of noncompliance with respect to human subjects research conducted under the auspices of the University's IRBs, responding to complaints or other inquiries from research participants, developing corrective and preventive action plans, and notifying federal oversight agencies of reportable events. Allegations of noncompliance may be received from IRBs, faculty, research staff, Institutional Officials, departmental administrators, research subjects, federal and state regulatory agencies, the media, or the general public. The COT also conducts routine (i.e., "not-for-cause") audits and provides consultations to the IRBs for compliance matters.

B. CU Office of Research Administration

The University-wide Office of Research Administration (ORA) was established in May 2013 to oversee the operations of both the Office of Sponsored Projects Administration (SPA) and the Clinical Trials Office (CTO).

1. Office of Sponsored Projects Administration

SPA is responsible for the administration of most sponsored research conducted by Columbia. The office works closely with the HRPO staff to ensure that all human subjects research has obtained appropriate IRB approval.

2. Clinical Trials Office

The CTO was formed by both NYP and CUMC to negotiate and manage agreements for industry-sponsored clinical trials and clinical research. The CTO fosters the ethical conduct of research by establishing important provisions and policies that are relevant for the protection of human subjects. The CTO also administers the Research Pharmacy, the Investigational New Drug (IND)/Investigational Device Exemption (IDE) Assistance Program, the Clinical Trials Monitoring Assistance Program, the RecruitMe project and the Spanish Translation Center.

C. Office of Research Compliance and Training

The Office of Research Compliance and Training (RCT) helps ensure that Columbia faculty and staff are in compliance with the complex web of regulatory requirements that govern research. RCT collaborates with many other offices to foster an integrated research compliance program. RCT administers the University's conflict of interest review process for research, serves as a resource for international research compliance issues, and administers Columbia's Standing Committee on the Conduct of Research, which addresses issues of research misconduct. RCT works to integrate compliance education programming across the University, and to develop new programming that promotes understanding of compliance issues throughout the research enterprise.

D. Conflicts of Interest Committee

The COI Committee reviews and determines the appropriate management or mitigation of any COI in accordance with Columbia's COI policy. The Rascal system facilitates the management of conflicts of interest by identifying any positive response for conflicts in either the Columbia annual COI disclosure statement or the protocol specific COI form. [ASK NAOMI TO REVIEW]

E. Joint Radiation Safety Committee, Radioactive Drug Research Committee, and the Radiation Safety Office

The Joint Radiation Safety Committee (JRSC) was created in 1991 by an Agreement among P&S, NYP, and NYSPI. The JRSC, in accordance with New York City (NYC) regulatory requirements, is responsible for oversight of the use of all sources of radiation and licensed radioactive material at these institutions.

Researchers who propose to use radiation or radioactive materials must submit a JRSC Application for Use of Radiation Involving Human Subjects (the JRSC Application) in Rascal as Hazardous Materials Appendix H to the related IRB protocol. The JRSC Application will first be reviewed by a Radiation Safety Officer and then submitted to the Human Use Subcommittee for a final vote of approval or disapproval.

The Columbia Radioactive Drug Research Committee (RDRC), created in the 1950s, is authorized by the FDA to review and approve the use of radioactive drugs that are recognized as safe and effective in human subjects during the course of certain basic science research projects. The Radiation Safety Office (RSO) is the professional, technical and administrative arm of the JRSC and RDRC and manages review and approval of applications for use of radiation involving human subjects.

F. Institutional Biosafety Office

The Institutional Biosafety Committee (IBC) is responsible for the review and approval of the handling of hazardous materials in research, such as potentially infectious tissues or bodily samples, and research involving gene transfer. [ASK KC TO REVIEW]

G. Protocol Review and Monitoring Committee

The Protocol Review and Monitoring Committee (PRMC) serves as the scientific review committee for the Herbert Irving Comprehensive Cancer Center at the CUMC campus. Protocols in the Rascal IRB module are accessible to the PRMC for review purposes, and both returns and approvals by the PRMC are documented in the IRB module.

H. Irving Institute for Clinical and Translational Research

The Irving Institute provides outstanding support and resources to Columbia University researchers including biomedical informatics services, biostatistics and research design, data management, community engagement, regulatory and bioethics support, clinical research

facilities, pilot funding programs, access to the Clinical and Translational Science Award (CTSA) Trial Innovation Network, and core laboratory resources. As part of the CTSA program, the Irving Institute houses an integrated educational program that includes short-term training, a patient-oriented master's degree, a novel KL2 mentored research program in multi- and interdisciplinary research, and a TL1 training program with three distinct tracks for doctoral students, postdoctoral fellows, and a 12-week summer program. In addition, the Irving Institute hosts several ongoing seminar series, research events and special symposia. In its current CTSA grant funding cycle and in synergy with a major Columbia University initiative in precision medicine, the Irving Institute initiated multiple new programs in precision medicine including education, training, and fellowships, an institutional biorepository, biomedical informatics, translational therapeutics, and community precision health.

I. NYP Pharmacy

The NYP Pharmacy works closely with the CUMC Research Pharmacy and the HRPO to ensure that investigational drugs, including those administered for emergency use, are administered in accordance with federal regulations, accreditation standards, and IRB and institutional policies.

J. NYP Patient Services Administration (PSA)

The NYP PSA and the Columbia Doctors Patient Services Office are available to: 1) ensure that patient rights are upheld; 2) assist with the resolution of problems or concerns, 3) provide information about hospital services and policies, and 4) connect patients with appropriate departments. As a result, these offices serve as a possible repository of concerns expressed by research subjects. They have established a close working relationship with the HRPO to ensure that any concerns from research subjects who participate in human research conducted at NYP on the CUMC campus are addressed satisfactorily.

K. Department Chairs, Faculty, Research Investigators, and Staff

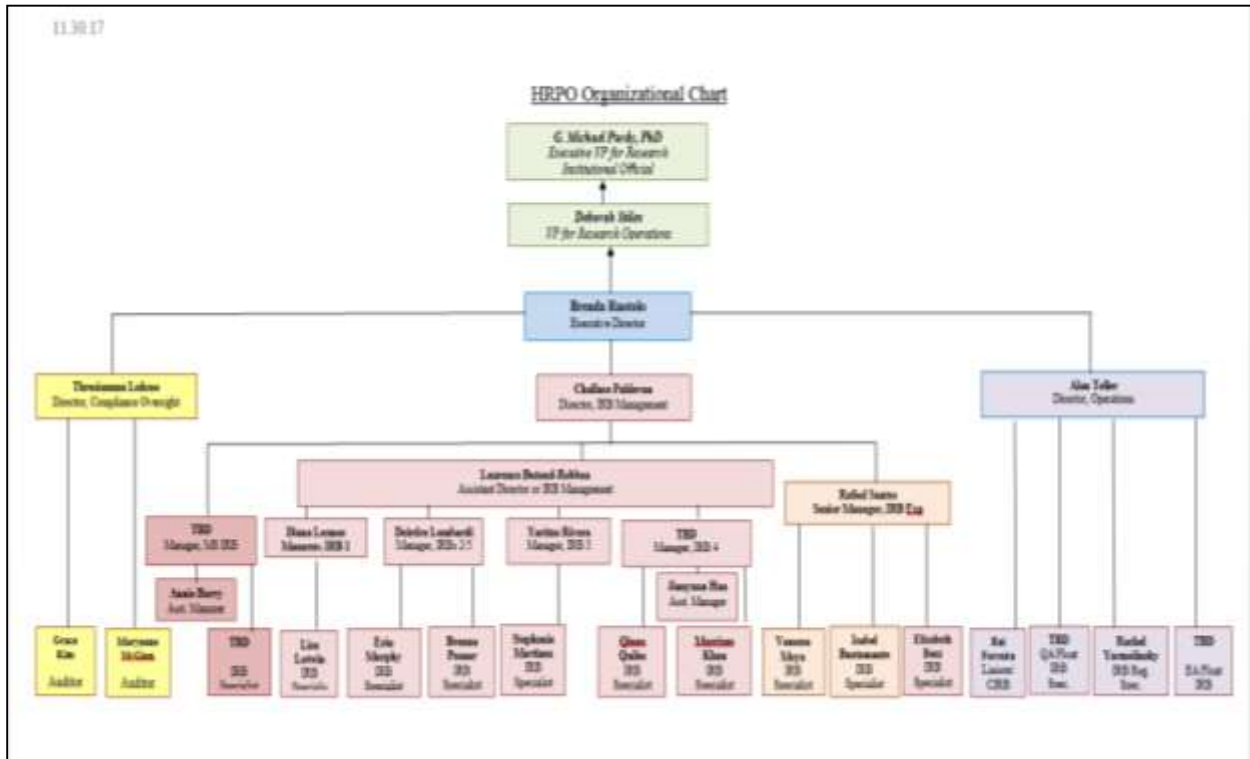
The Department Chairs and faculty are responsible for ensuring that all research involving human subjects is conducted in accordance with ethical principles, institutional policies, and federal and state regulations. The leadership provided by the Department Chairs, faculty, and administrators helps to ensure that research at Columbia is conducted with high quality and in an ethical manner. The research investigators and staff are at the forefront of human research protections, as they are best positioned to directly ensure that research is conducted ethically.

L. Office for HIPAA Compliance (OHC)

The IRBs serve as the Privacy Boards for research-related HIPAA activities. The OHC provides review, support and oversight for certain research-related HIPAA requirements for protocols submitted to the IRB.

M. Reporting and Effective Communication between Offices

Each of the above mentioned offices will inform the IRB, and vice versa, of any concerns expressed by research subjects or any potential noncompliance with the regulations for human subjects protection.



EVPR Organizational Chart

