

Columbia University
Human Research Protection Program
Executive Summary
July 29, 2013

I. Name:

- Name for posting on the AAHRPP website: Columbia University/Columbia University Medical Center
- Components and Major Administrative Units:
 - Columbia University
 - 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. 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 and conduct of human research at Columbia, including the Columbia University Medical Center (CUMC), and New York Presbyterian Hospital (NYP) on the CUMC campus. CU has two Federalwide Assurances (FWAs): one for CUMC and one for the main campus at Morningside Heights (CU-MS). NYP has its own FWA and is a separate legal entity from CU. Although there are three FWAs, the Columbia HRPP is responsible for all human research conducted at CUMC, CU-MS, and NYP, or by any affiliated faculty, employees, or staff of CU and NYP regardless of location.

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 Institutional Review Boards (IRBs) is the senior officer responsible for the day-to-day administrative and management oversight of the HRPP, and for the management of all IRBs at CU. The ED reports to the EVPR, through Deborah Stiles, Vice President for Research Operations (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, Interim Executive Director, IRB
Alan Teller, Asst. Director, IRB Operations

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 IRB:

Jane Booth, J.D., General Counsel

IRB Chairs and Vice Chairs

CUMC IRB#1: Marilyn Morris, M.D., Chair; Deborah Bell, Vice Chair
CUMC IRB#2: Elaine Larson, Ph.D., Chair; Lawrence Bodenstein, M.D., Vice Chair
CUMC IRB#3: Neil Schluger, M.D., Chair; Katherine Biagas, M.D., Vice Chair
CUMC IRB#4: Balazs Halmos, M.D., Chair; Alice Lee, M.D., co-Vice Chair; Prakash Satwani, M.D., co-Vice Chair
CUMC IRB Exp: Marilyn Morris, M.D. Elaine Larson, Ph.D.;
Neil Schluger, M.D.; Balazs Halmos, M.D., Chairs
MS IRB: Andrew Nathan, Ph.D., Chair; Robert Downs, Ph.D., Vice Chair

IRB Officer Staff:

IRB 1: Challace Pahlevan, Manager; Scott Beardsley, Assistant Manager
IRB 2: Rachel Lally, Manager; Anita Ou, Board Coordinator
IRB 3: Leigh Travis, Manager; Lynda Mules, Assistant Manager
IRB 4: Laurence Butaud-Rebbaa, Manager; Yaritza Rivera, Assistant Manager; Amy Paige, Board Coordinator
IRB Expedited Review: Susie Kim, Manager; Vanessa Moya, IRB Specialist; Prena Zagreda, IRB Specialist
IRB Morningside: Joyce Plaza, Manager; Annie Barry, IRB Administrator; Rafael Santos, IRB Administrator
Compliance Oversight Team: Jessica Randall-Aprea, Manager; Vanessa Laroche, Auditor; Diana Wong, Auditor; Daniel Matulich, Auditor
Quality Assurance/IRB Specialist: Hegulka Scheiman

Pharmacy Representatives responsible for control of investigational drugs:

Rudina Odeh-Ramadan, Pharm.D., Interim Director, Research Pharmacy
Richard Fichtl, 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., Associate VP for Research Compliance & Training

Individuals responsible for reviewing and signing grants and sponsor contracts:

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

Key personnel for affiliated organizations:

Richard Liebowitz, M.D., M.H.S., Senior Vice President and Chief Medical Officer,
NYP (Institutional Official on NYP FWA)
Sharon Ferguson, Director, Patient Relations Department (liaison for compliance)
Edward Nunes, M.D., IRB Co-Chair, New York State Psychiatric Institute (NYSPI)
Daniel Richter, M.D., IRB Co-Chair, 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, faculty members also actively conduct research at other sites, both domestic and international. Furthermore, many Columbia faculty members collaborate on projects with investigators at other institutions.

The Columbia HRPP includes approximately 3,000 faculty members and accounts for approximately 1,700 new human subjects research studies each year. 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 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) ICH-Good Clinical Practice (E6) to the extent it is consistent with FDA Regulations; 4) the Department of Education Family Education Rights and Privacy Act (FERPA); 5) New York State Laws 2440/441 and Article 7, Section 79-1 (Confidentiality of Genetic Tests); 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. The Morgan Stanley Childrens Hospital is a component of NYP at CUMC. All policies and practices of the HRPP apply to research conducted at any of NYP, Morgan Stanley Childrens Hospital, 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. Columbia IRB:

The mission of the CU IRB is to enhance and facilitate the ethical conduct of human subjects research conducted by Columbia, and by Columbia faculty, regardless of location. The CU IRB will perform this mission through its review of human subjects research, its educational and training initiatives, and its compliance oversight and quality improvement programs.

1. IRB Office

The IRB Office 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 IRB office is attached on page 7.

The IRB Office 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 IRB Office 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 IRB Office has two locations: a) one office at CUMC, and b) a second at CU-MS.

Four committees in the IRB Office support initiatives to improve the ethical conduct and review of research: 1) Educational Training Committee, 2) Policy Committee, 3) Accreditation Committee, , and 4) RASCAL Committee. The purpose of each committee is discussed in more detail below.

2. Institutional Review Boards

There are six IRBs in the Columbia HRPP. Five IRBs (four full-board, one expedited review) are responsible for review of human subjects research conducted by faculty, employees, staff, and students at CUMC and NYP and one IRB is responsible for human research conducted by faculty, employees, 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.

3. External IRBs

CUMC and NYP have IRB Authorization Agreements with the New York State Psychiatric Institute (NYSPI), the Weill Medical Center of Cornell University, the National Cancer Institute Central IRB (CIRB), CU-MS, Massachusetts General Hospital/Partners (central IRB for the NeuroNEXT trials), Fred Hutchinson Cancer Center (central IRB for the HVTN studies) and the Western IRB (WIRB) to rely on reviews by their IRBs for certain types of research projects. Details regarding each agreement are provided in the IRB Standard Operating Procedures (SOPs).

4. Compliance Oversight Team

The Compliance Oversight Team (COT) is responsible for investigating and handling all allegations of noncompliance and complaints with respect to the protection of human subjects in research. 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 not-for-cause audits.

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. Sponsored Programs Administration

SPA is responsible for the administration of most sponsored research conducted by Columbia. The Office works closely with the IRB 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 manages clinical trials and clinical research not administered by SPA. 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 IND/IDE Assistance Program, the Clinical Trials Monitoring Assistance Program, and the Spanish Translation Center.

D. Research Compliance and Training Office

The Research Compliance and Training Office (RCT) develops and provides educational training initiatives for all research administration offices that do not have their own education training or compliance programs. RCT also provides several compliance oversight efforts. One such effort is to administer and manage any noncompliance involving research integrity (i.e., fabrication, falsification or plagiarism). The RCT also provides administrative assistance and works closely with the Conflicts of Interest (COI) Committee and manages the review of all conflicts of interest involving research conducted at Columbia.

E. 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.

F. 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.

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.

G. 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.

H. 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.

I. Irving Institute for Clinical and Translational Research

The Irving Institute for Clinical and Translational Research currently provides resources to foster and support new collaborative, multidisciplinary human subjects research at Columbia. Resources provided include consultation for biomedical informatics, research design and biostatistics, and regulatory considerations. The Institute also administers the Clinical Research Center which allows investigators to conduct both inpatient and outpatient studies involving adults and children.

J. NYP Pharmacy

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

K. NYP Patient Services Administration

The NYP Patient Services Administration (PSA) staff is 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, this Office serves as a possible repository of concerns expressed by research subjects.

L. 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 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.

M. Privacy Office

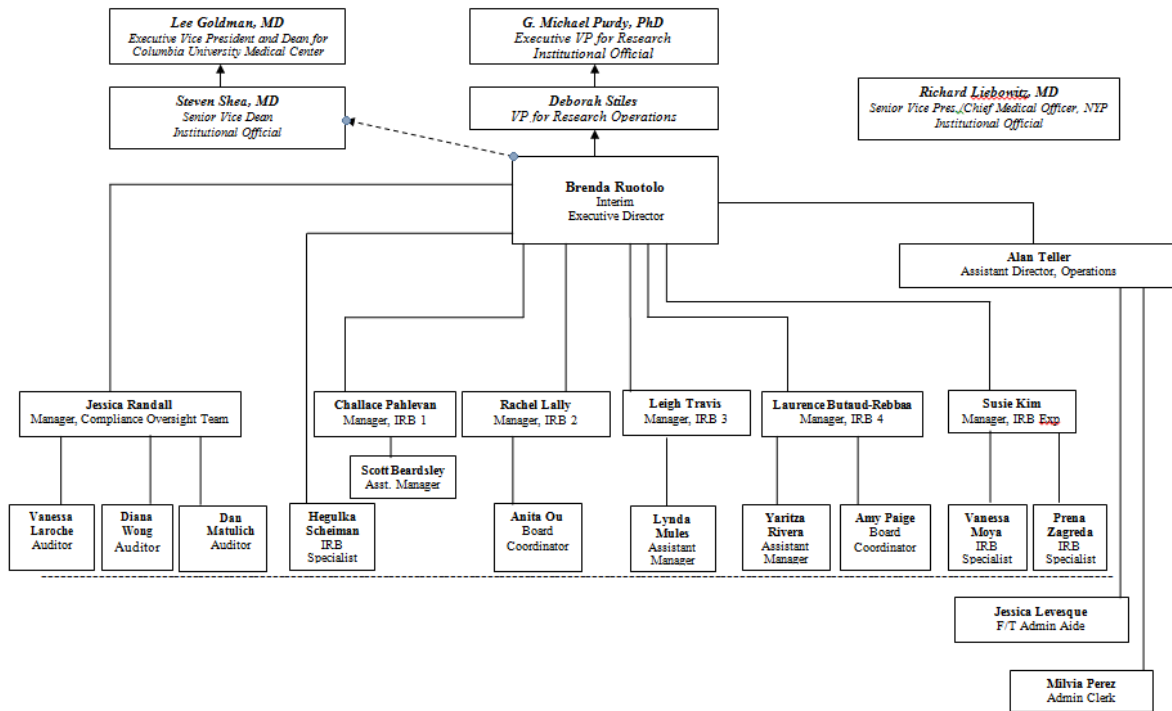
The IRB serves as the Privacy Board for research-related HIPAA activities. The HIPAA Privacy Office provides review, support and oversight for the research HIPAA requirements for protocols submitted to the IRB.

N. 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.

July 2013

CU IRB Organizational Chart (CUMC IRB)



Jan 2013 v2

CU IRB Organizational Chart (MS IRB)

