Dear Graduate Students and Faculty Sponsors,

Columbia University operates under a Federalwide Assurance (FWA) with the Office for Human Research Protections (OHRP) that regulates the conduct of research involving human subjects. Compliance with this Assurance requires the University to ensure that all human subjects research conducted under the auspices of the institution is reviewed and approved by the Institutional Review Board (IRB) prior to the conduct of the research. Institutions are expected to provide a comprehensive, ongoing training program in basic human subjects protections and to verify that all applicants submitting protocols for IRB approval have undergone this training.

The Columbia IRB at Morningside (CU-MS IRB) oversees human subjects research for faculty and students on the Morningside and Lamont campuses. Students from Teachers College or Barnard should seek approval from the IRB at those institutions. Staff at any of these IRBs can provide guidance on research that may require review from multiple institutions, if needed.

All Columbia faculty, employees, and students who propose to conduct research involving human subjects, whether funded or non-funded, are required to:

1. Complete the appropriate web-based training program(s) on the protection of human research participants prior to submitting their research application to the IRB Office. The training can be found on Columbia’s Rascal website – Testing Center link (https://www.rascal.columbia.edu/).
   a. The required basic training for all researchers is TC0087 - Human Subjects Protection Training.
   b. Additional training is required if the research involves minors (Research with Minors, an option in TC0087).
   c. TC0019 - HIPAA: Health Insurance Portability Accountability Act Research Training Course is required if protected health information (PHI) is collected or created during the study.

2. Submit their research to the IRB for review and approval. Protocols that are exempt from the requirements of the regulations also need to be reviewed by the IRB for an exempt determination. All IRB applications must be submitted electronically through Rascal at https://www.rascal.columbia.edu/.

The Graduate School of Arts and Sciences requires all faculty advisors and graduate students to determine whether or not their current or prospective research involves the use of human subjects and, if so, to complete the applicable web-based training program(s) immediately and apply for review and approval by the Morningside IRB. Failure to do so may result in serious penalties to the University and yourself, such as the discarding of your research findings and the prevention of the publication of your results. The Columbia Students as Researchers Policy also requires submission of some projects that may not meet the regulatory definitions of “research” but involve humans or data about them.

Note that the Principal Investigator must be a full time member of the faculty (Officer of Instruction, or an Officer of Research, at specific ranks as described in the Faculty Handbook. The Faculty Handbook can be found online at: http://www.columbia.edu/cu/vpaa/fhb/ (See “Obligations and Responsibilities of Officers of Instruction and Research.”)

For student research, the faculty advisor, or other appropriate faculty member, should be listed as PI on the student’s IRB application. Students may be co-investigators.

If you need guidance to determine whether or not you are conducting research involving human subjects, you may contact the CU IRB Office at 212-851-7040.

For information on the web-based training program and information on submitting a protocol, see the Morningside IRB website at http://www.columbia.edu/cu/irb/.
A short web-based Rascal training module (not required) that illustrates how to create and submit a protocol in Rascal.js available via the Rascal Testing Center link: TC0017 - Rascal Training: How to do Human Subjects Protocols.

Faculty sponsors/PIs are ultimately responsible for the conduct of all student research and should familiarize themselves with IRB policies.

The CU IRB policy on Students as Researchers can be found at: http://www.columbia.edu/cu/irb/documents/StudentresearchPolicy031612FINAL.pdf. For guidance that provides practical information that will facilitate the submission of student research proposals see: http://cait.columbia.edu:88/dept/irb/policies/documents/StudentresearchguidelinesFINAL031612.pdf.

An information session on human subjects research and IRB protocols will be held tomorrow:

**IRB 101: Human Subjects Research Protections and How to Submit a Protocol to the Institutional Review Board**
Friday, September 14, 1:00-2:30 p.m. 603 Hamilton Hall
If your study/project involves research with human subjects such as interviewing, administering questionnaires or surveys (including Mechanical Turk and Survey Monkey), conducting focus groups, collecting data “about” people, or reviewing identifiable data previously collected, then you need to submit a protocol for approval by the CU IRB before you begin. If you are planning to conduct Human Subjects Research and will be submitting to the IRB for approval, consider attending this session.