

Date: December 28, 2002

To: Faculty, Researchers and Administrators on the Morningside Campus

From: Jonathan R. Cole, Provost and Dean of Faculties

Subject: Human Subjects Training

About a year ago I wrote you about the federal requirement that all individuals conducting research with human subjects undergo training in this area. All members of the faculty, research and administration who carry out research using human subjects, regardless of whether or not the work is federally funded, are required to receive this training.

For our purposes, "research" is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. A "human subject" is defined as a living individual about whom an investigator (whether a professional or a student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.

According to our negotiated Assurance of Compliance, all human subjects research conducted by individuals in their capacity as a member of the university community, whether that research is funded or not, must be reviewed by the University's Institutional Review Board (IRB) or the University stands to lose millions of dollars of sponsored project funding from the federal government.

Last summer I asked an *ad hoc* committee to develop new training materials applicable to the types of research conducted by Morningside faculty and administrators.

This new training program is now available on the University's RASCAL website at <<https://www.rascal.columbia.edu>> (select the Testing Center within the Compliance module) to access this program.

Since the federal government requires that individuals involved in human subjects research demonstrate their "competency" the *ad hoc* committee has also created an examination based on the newly developed training.

As of February 1, 2003, the Morningside IRB will require all individuals working with human subjects to take the RASCAL course and present evidence of its passage. All individuals on the Morningside Campus **who have not taken the previously posted NIH course (and who have not logged into RASCAL and completed their Personal Information Page)** are now required to take this new course and examination in order to receive permission to work with human

subjects. At the end of this exam you will be able to print up a certificate for your records. It should take less than an hour for you to complete the training and take the examination.

The Office of Projects and Grants has posted a decision-tree on its website <<http://www.columbia.edu/cu/opg/policies/policies.html>> - under Human Subjects – which can be of help to you in determining whether your project does, indeed, use human subjects. If you have any questions about the exact procedures for your project, or if you have any questions about the content of the examination, please contact the IRB directly at 854-1324 or via email at <askirb@columbia.edu>.

I realize that many of you will feel that this is an inconvenient and bureaucratic requirement. While we would all agree that the protection of human subjects is an important ethical concern for researchers, some may find the bureaucratic nature of the federally-required process of training and certification problematic. Whatever one thinks, we must comply with these federal regulations. I thank you, in advance, for your cooperation and compliance.