To: Columbia Human Subjects Research Community
Subject: Two New Human Subjects Protection Training Requirements
Date: Oct. 19, 2010

Columbia University is committed to the highest ethical and compliance standards when it comes to the protection of human subjects who participate in Columbia research. In keeping with best practices, we are launching two new mandatory training requirements: (1) mandatory refresher training in the protection of human research subjects for all human subjects researchers (effective **March 31, 2011**); and (2) mandatory training for all clinical research coordinators (effective **January 1, 2011**).

1. Refresher Training for All Human Subjects Researchers

Many of our peer institutions have implemented refresher training requirements in the protection of human subjects for all human subjects researchers. Columbia similarly will be implementing a refresher training requirement to be in full effect by **March 31, 2011**.

As you may know, in Spring 2009, the University switched its Human Subjects Protection (HSP) training requirement to the web-based Collaborative Institutional Training Initiative (CITI) for new human subjects researchers. Since then, more than 4,000 researchers have completed CITI training.

Now, all Columbia researchers who have not already completed the CITI training course must do so as refresher training, even if they took a Columbia HSP (GCP) training previously. The CITI course includes seven modules and takes 3-4 hours to complete. It does not need to be completed in one sitting and can be completed at your convenience.

As of **March 31, 2011**, the IRB may not approve an initial human subjects research protocol, or a modification or renewal of an existing protocol unless all researchers listed on the Data Sheet have completed CITI training.

Once the 7-module CITI training has been completed, an abbreviated CITI refresher training will be required **every three years**. Those researchers who have already completed CITI training will be notified when the time for refresher training approaches.

The CITI Human Subjects Protection course can be accessed through the Rascal Training Center: Course TC0087: Human Subjects Protection Training. A list of frequently asked questions about Human Subjects Protection training can be found on the IRB website. If you have questions about the new requirements, please contact the IRB at irboffice@columbia.edu or the Office of Research Compliance and Training at research-compliance@columbia.edu.

2. Clinical Research Coordinator Training

Columbia's new Clinical Research Coordinator (CRC) training requirement takes effect **January 1, 2011.** The objective of the CRC Training Program is to review the roles and responsibilities of the CRC, including regulations concerning documentation, data management and other

requirements, as well as the specifics of conducting research at CUMC. The program consists of 5 video podcast presentations, available online, and self-study of the Clinical Research Handbook. An assessment must be completed in the Rascal Training Center.

The CRC Training Program is open to all research personnel who are involved in work with human subjects or collection and maintenance of study data. It is mandatory for individuals who participate in clinical human subjects research that involves more than minimal risk and who are designated under "Personnel Staff" on any Rascal Human Subjects Protocol Data Sheet as having one of the following roles:

- Study Coordinator
- Research Coordinator
- Research Nurse
- Regulatory Coordinator
- Data Manager
- Research Assistant

As of **January 1, 2011**, the IRB may not approve an initial protocol or a modification or renewal of an existing protocol unless the Data Sheet indicates that all such CRCs have completed the CRC Training Program. No such CRC may commence conducting or continue to conduct any research activities under any protocol prior to obtaining IRB approval.

The CRC Training Program can be accessed through the RASCAL Training Center: Course TC0098: Clinical Research Coordinator Mandatory Training. If you have questions about this new requirement, please contact the Clinical Trials Office at CTOinformation@columbia.edu or the IRB at irboffice@columbia.edu. The policy for training of CRCs can be accessed at: http://www.cumc.columbia.edu/dept/irb/education/index.html#CRC

Thank you for your attention to these important matters.

Sincerely,
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