

Date: February 27, 2009

To: Columbia Research Community

From: George Gasparis
Executive Director, Institutional Review Board

Re: Human Subjects Protection Training Program

Columbia is adopting a new Human Subjects Protection training program: the nationally-recognized and widely-used Collaborative Institutional Training Initiative (CITI) on-line human subjects protection training modules. As of March 4, 2009, any human subjects researcher, including students, postdocs and others, who has not previously completed one of the current CU human subjects protection training courses in Rascal will be required to complete CITI training as a prerequisite for IRB approval.

At this time, if you already completed training in human subjects research at Columbia, you are not required to complete the CITI training, other than the CITI module for research with children if you will be engaged in such research.

Why CITI?

Columbia chose CITI training because the content is extensively reviewed, critiqued and updated, participant satisfaction is high, and the program was recommended by a faculty work group. In addition, the CITI training offers a modular structure that can be tailored to individual researcher needs. Finally, CITI is easily accessible on the World Wide Web and will interface with the University's electronic research compliance and administration system, Rascal.

We established the new requirements after surveying our peer institutions' human subjects training requirements. Our survey showed that peer institutions require completion of between 6 and 18 CITI modules. As explained below, Columbia has established a 7-module requirement. We recognize that many in the research community are already fulfilling a variety of other training requirements. We are currently conducting a comprehensive review of all required training for researchers and staff, in order to rationalize the requirements and to minimize any duplication imposed by this training initiative.

What is required?

Under the new requirement, each researcher will be required to complete a total of seven modules - 5 core modules and 2 additional modules. Depending on the type of research, CITI will assign a researcher to the appropriate "Learner Group." Some Learner Groups will specify all seven required modules (e.g., biomedical research with children and FDA-regulated research). However, most Learner Groups will afford the investigator the opportunity to select one or two of the seven modules, and thus choose the modules most applicable to their research. Researchers who conduct research with children will

continue to be required to complete the CITI Research with Minors module. In addition, researchers conducting FDA-regulated research will need to complete a module on FDA regulations.

Each module takes between 10 and 20 minutes to complete. Completing all the required modules will take between 1.5 and 2.5 hours. All modules do not need to be completed at one sitting; CITI will automatically mark your place and return to it at a later time. Except for the Introduction, each module includes a brief quiz. CME credit is available.

In order to ensure documentation in Rascal, you must access the course via the Rascal Training Center at <https://www.rascal.columbia.edu/tclogin.html>.

Customization with CITI

One of the benefits of the CITI program is that it includes a curriculum track customized for researchers in the social sciences and humanities who are conducting human subjects research (the Social/Behavioral Research, or SBR, track). These modules were especially developed to address social and behavioral research issues, and include topics such as Internet research, research in public secondary and elementary schools, and assessing risk in social and behavioral research.

If You Have Questions

The transition to CITI training is being led collaboratively by the IRB and the Office of Research Compliance and Training. Attached is a list of Frequently Asked Questions. Additional information about the CITI requirements, including the FAQs, is available on the IRB's website at <http://www.columbia.edu/cu/irb/>. Please feel free to contact the IRB at 212.305.5883 or irboffice@columbia.edu or the Office of Research Compliance and Training at research-compliance@columbia.edu with any questions about this new requirement. We also encourage you to explore additional human subjects protection training opportunities offered by the IRB and the CTSA, as well as CITI.

Thank you for your efforts to enhance the ethical conduct of research and the protection of human subjects.