



June 22, 2009

New IRB Policy Regarding Review of Research by Western IRB

Dear Colleagues:

Effective July 15, 2009, the Columbia IRB office will no longer grant permission for review by the Western IRB (WIRB) of industry-supported Multicenter clinical trials involving investigational drugs or devices. In addition, protocols for which the WIRB is the IRB of record will transition back to CUMC IRB review at the time of renewal, beginning with those with WIRB expiration dates of September 15, 2009.

The Columbia IRB commends the Western IRB (WIRB) for their collaboration and efforts to review the above mentioned studies in recent years. Reliance upon the WIRB has offered the opportunity for the Columbia IRB to refine and improve many of its processes (newly implemented processes to reduce burden or improve efficiency are provided below).

Over the past few years, the Columbia IRB office has developed a comprehensive human research protection program (HRPP) that is inclusive of a robust education and training program, and an active compliance oversight initiative. In February 2009, a fourth IRB, designed to focus on reviews of oncology research studies, was added at CUMC. All industry-supported oncology trials involving investigational drugs/devices that had previously been submitted to WIRB are being transitioned to the fourth IRB, in a process that began in March 2009.

Another key area of improvement is the performance of all of the Columbia IRBs. Metrics of turnaround time over the past three years indicate that total regulatory approval time is comparable for studies reviewed by either the Columbia IRB or WIRB (that is, the total time for all regulatory approvals of human subjects research, such as IRB, Cancer Center, Conflicts of Interest Committee, HazMat reviews including Institutional Biosafety Committee and Radiation Safety, and satisfaction of Columbia's education and training requirements). We are finding many studies, including clinical trials, that have turnaround times of less than 60 days from submission to final approval of all regulatory reviews.

Because of these improvements, after much preparation the Columbia IRB office submitted an application for accreditation of the Columbia HRPP in January 2009.

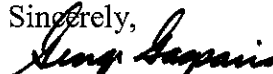
We are striding for even more significant improvements in the quality and efficiency of reviews by the Columbia IRB. In regards to efficiency, while turnaround time in general is acceptable,

review of our performance data still reveals too many studies that take three months or longer for approval. In addition, feedback from investigators indicates that the submission process may be burdensome. With respect to improvements in quality, the Columbia IRB has initiated several efforts to confront challenging regulatory or ethical dilemmas on a national level. Interactions with leaders of our industry and the federal regulatory agencies are providing clarity and solutions to some of these challenges.

Therefore, to further improve efficiency and reduce burden, we are implementing the following changes:

- 1) We have developed a new abbreviated submission process for multicenter studies supported by industry or NIH cooperative groups (e.g., ACTG, HVTN, NCI oncology group studies, etc.). The new process will still require completion of all RASCAL fields that provide information regarding local implementation of the study. However, entering of the study summary into the Study Description field will no longer be required, as the Columbia IRBs will now rely on the sponsor's protocol for review by all of its IRB members). The new process can be found at:
<http://www.cumc.columbia.edu/dept/irb/documents/AbbreviatedIRBSubmission.061809.pdf>
- 2) For protocols that are transitioning back to CUMC IRB review, the Columbia IRB office will convert pdf documents of WIRB-approved consent documents (English and translated versions) to a version that can be stamped by the IRB staff, if no changes to these documents are required by the CUMC IRB that is conducting the review.
- 3) A new policy will go into effect on September 1, 2009, requiring withdrawal of returned new studies for which the IRB has not received a response within 90 days of receipt of the IRB correspondence that explains the return and articulates the IRB requests. In these situations, the investigator will need to submit the protocol under a new IRB number. The IRB staff and/or RASCAL will send periodic reminders to the investigator to prevent such withdrawal.
- 4) Starting this summer, the Columbia IRB will begin convening workshops for investigators and research staff to improve their skills in writing informed consent documents. Some workshops will be held in a computer lab and will allow hands-on training to enhance such skills. By improving the quality of the informed consent documents submitted to the IRB, we will be able to further improve the turnaround time of IRB reviews. Other consent workshops or seminars will be designed to enhance the informed consent process as well as the consent form.

The Columbia IRB is committed to providing the best service possible to our research community. Together, we can further enhance the ethical conduct of research. We thank you for your support and your feedback.

Sincerely,

George Gasparis
Columbia IRB