

# Memo

Research Subject Protection Program

**Date:** 8 April 2008  
**To:** Investigators, Research Staff, and Sponsors  
**From:** Lori Roesch, CIM, CIP, Manager, Research Subject Protection Program  
**Re:** Summary of Aurora IRB Policy: “Problems that Require Prompt Reporting” (RR 403)

The following is a summary of the Aurora IRB policy identifying problems that require prompt reporting (SOP RR 403). This policy encompasses reporting of “adverse events”, injuries to subjects or others, new information, complaints, protocol violations, etc. (a more complete, but not exhaustive, list is found in the policy). This policy was approved on 15 February 2008 to better facilitate the IRB’s review of adverse events and other unanticipated problems to ensure the IRB’s continued compliance with the federal regulations as well as AAHRPP accreditation standards.

**Local and External Unexpected Events** that meet the following criteria must be reported promptly to the IRB within 10 working days of discovery (this includes all events, whether “serious” or “not serious”).

- Unexpected\*\* (i.e. not listed in investigator’s brochure or current risk information);

**AND**

- Related, or probably related, which means that in the opinion of the *local investigator*, the event is more likely than not to be caused by the research procedures or it is more likely than not that the event affects the rights and welfare of current subjects (a guideline for determining whether an event is “probably related” would be a greater than 80% likelihood that the event is related to the research procedures).

All events must be reported to the Aurora IRB using the appropriate reporting form along with any additional supporting documentation relating to the event. These forms can be found on the RSPP web site located at: <http://www.aurora.org/irb> (Form RR 403-A for local events and Form RR 403-B for external events).

***All other local or external events that do not meet the above criteria, but are required by the sponsor to be reported to the IRB, should be compiled and submitted at the time of continuing review.*** A sample spreadsheet for reporting events at the time of continuing review is available on the RSPP web site.

**\*\*Please note:** For both local and external events, if the event is expected (i.e. described in the investigator’s brochure or other current risk information) but has occurred more frequently than anticipated (as determined by the *local investigator*), or is more serious than expected, such that subjects or others may be at risk (as determined by the *local investigator*), the Aurora IRB considers this to be an “unexpected” event, and as such should also be promptly reported.

At the time any report is received, if the sponsor or *local investigator* is not able to make a determination that the event is related or probably related to the research, the event should not be reported promptly to the Aurora IRB. Once a relatedness determination has been made, the *local investigator* can decide whether the event meets the criteria for prompt reporting to the Aurora IRB. The 10 working day reporting deadline begins once the *local investigator* is aware that the event is related to the research.

Any reports received by the Aurora IRB that do not meet the above reporting requirements will be returned to the investigator, and can be compiled and submitted at the time of continuing review.

Please direct any specific questions regarding this policy to the RSPP office at 414.219.7744.