

Memo

Date: 8 June 2011
To: Investigators, Research Staff, and Sponsors
From: Lori Roesch, CIM, CIP, Manager, Research Subject Protection Program
Re: *Summary of Aurora IRB Policy for LOCAL Unanticipated Problems Requiring Immediate Reporting*



Research Subject
Protection Program

Local Unanticipated Problems that meet the Aurora IRB policy definition must be reported within five (5) working days of the investigator becoming aware of the problem (this includes all events, whether “serious” or “not serious”). “Local” events are those that occur at a site for which the Aurora IRB has oversight. The following criteria must be met and documented:

1. **“Unexpected”** means that the specificity and severity are not accurately reflected in the information previously submitted to the IRB (e.g. protocol, Investigator Brochure and/or informed consent document). [Note an event is considered “unexpected” if it is occurs at a specificity or severity that is inconsistent with prior observations, such as what is described or addressed in the information previously submitted to the IRB.]
2. **“Possibly Related Or Related To The Research Procedures”** Possibly Related means there is a reasonable possibility that the incident, experience or outcome may have been caused by the procedures involved in the research. Reasonable means a strong temporal relationship to the study protocol, and implies that an alternative etiology is unlikely or significantly less likely. Related means related to the use of the research procedure and implies a definitive relationship.

All local events that meet the above criteria must be reported to the Aurora IRB using the **Local Unanticipated Problem Reporting Form (Form RR 403-A)**. This form can be found on the RSPP web site. Additional questions about problem will need to be addressed. One consideration is whether the problem has implications for the conduct of the study (e.g., requiring a significant and usually safety-related change to the protocol such as revising inclusion/exclusion criteria or including a new monitoring requirement, informed consent or investigator’s brochure). This is referred to locally as a “Risk Mitigation Plan”.

The IRB will review the report to determine whether the report meets the policy definition of an “Unanticipated Problem Involving Risk to Subjects or Others” (“UPIRSO”). If the problem is determined to be a UPIRSO, the IRB will work with the investigator and sponsor to ensure that the problem is appropriately managed, and will report externally in accordance with Aurora IRB Policy RR 408.

All 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.

Any reports received by the Aurora IRB that do not meet the above reporting requirements will be returned to the investigator.

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