

Sent: Tuesday, October 14, 2008 8:38 AM
To: UKORI-IRB-L@LSV.UKY.EDU
Subject: Non-Prompt Reporting of External Adverse Events/Problems

Announcement/Reminder from the [Office of Research Integrity](#)

Investigators participating in multi-site research projects can receive numerous External Adverse Events/Problem Reports regarding subjects at sites other than UK or the VAMC. It is important for investigators to triage these reports the same way they would internal events to determine what meets the requirement for [prompt reporting](#) vs. what should be included in a qualitative and quantitative summary of cumulative events/problems with the continuation review. The rationale being that this reduces the total number of reports to allow thorough IRB review of those most critical and urgent.

Some sponsors, however, request that all external adverse events/problems be immediately submitted for IRB review. If a PI recognizes that a problem/event does not meet the prompt reporting requirements, (see examples below), the PI is encouraged to send the sponsor the [IRB's letter of explanation](#) about the UK IRB policy on review of events.

If the sponsor, after receiving the "Letter for Sponsors" (above), still requires the PI to submit reports to the IRB that do not require prompt reporting according to UK's policy, the PI may complete the [Cover Form for Non-Prompt Reporting of Problems/Events](#).

| Examples of incidents that fall under the UK Non-Prompt Reporting Policy . | |
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| Internal or External | Serious or life-threatening anticipated problems or adverse events |
| | Not serious or life-threatening anticipated problems or adverse events |
| | Unanticipated or anticipated death not related to the research (e.g., due to underlying disease) |
| External | Request by sponsor to submit event that does not require prompt reporting per UK IRB policy |

Of course, the investigator may choose to report additional events above and beyond the requirements of this policy if they notice trends or have any concerns whatsoever regarding subject safety and the risk-benefit ratio of the research.

BMS
 10/14/08