



The University of Michigan Medical School
Institutional Review Board for Human Subject Research (IRBMED)
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To Whom It May Concern:

On October 1, 2007, the Medical School Institutional Review Boards (IRBMED) posted new guidance for reporting adverse events (AEs) and other reportable information and occurrences (ORIOs). This update is in response to federal guidance from the HHS Office of Human Research Protections (OHRP) and draft guidance from the HHS Food and Drug Administration (FDA) issued this year.

Key Changes

1. **Effective 10/1/07** —Submission to the IRB of reports of single AEs that occurred at **non-UM** sites (external AEs, including those on multi-site trials) will be **required only** if one of these criteria is met:

- The AE is judged by the study sponsor, DSMB, or principal investigator (PI) to constitute an 'unanticipated problem involving risks to the subjects or others' (hereafter referred to as 'unanticipated problem'). Click here for detailed guidance on [unanticipated problems](#).
- The AE results in a change to the research (e.g. a change to the risk section of the informed consent document)

This change is effective October 1 even if the investigators received the reports prior to 10/1/07. The new federal guidance stresses that routine IRB review of external adverse event reports that do not constitute 'unanticipated problems' is an inappropriate allocation of IRB resources.

If the PI has another justification (e.g. it is required **by contract** with a sponsor) the IRB will accept a non-required report.

Note that this change in policy does not alter requirements for investigators to submit a report that is an analysis, safety, or statistical report from an oversight entity (e.g. FDA letter, Periodic Sponsor Report of all AEs, Data and Safety Monitoring Board Report).

2. **Effective 11/15/07** —Required timeframes for reporting will be in '**calendar days**' rather than 'working days.' This change will not be enforced until 11/15/07 to give investigators the opportunity to adjust to the shorter turnaround time.

For more information see the [IRBMED website](#) or email irbmed@umich.edu.

Sincerely,

Jan Hewett, JD, BSN
Director, IRBMED