



Comments for FDA public hearing [Docket No. 2005N-0038] “Reporting of Adverse Events to Institutional Review Boards; Public Hearing”

What can be done to provide IRBs adverse event information that will enable them to better assess the implications of reported events for study subjects?

**Consistent** reporting by sponsors/investigators so that the following issues are addressed for all reportable events

1. Aggregate information
  - a. How many subjects have experienced the same adverse event
  - b. How many subjects to date have been exposed to the study intervention.
2. Whether or not this event is listed in the investigator’s brochure (or whether the event was unanticipated)
3. Relatedness – especially “probably caused by” or “definitely caused by”

Consolidation and summarization of adverse events would be very helpful prior to IRB review.

**What information should be included in this summary (report)?**

- 1) Aggregate information
- 2) Number of subjects exposed to study intervention
- 3) Listed in investigator’s brochure
- 4) Relatedness
- 5) Unanticipated
- 6) Should changes be made to the informed consent? The study conduct?

**When should summary information be provided to IRBs?**

At least on a monthly basis

**Who should prepare these reports?**

Sponsor should prepare these reports on a monthly basis with DSMB reports submitted on their regular schedule as well.