

Reporting of Adverse Events to IRBs

Comments from Western Institutional Review Board

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WIRB Experience

- **12,000 site-generated AE reports annually**
- **14,000 sponsor-generated AE reports annually**

Resources for Review

- 3 FTEs entering data
- 2 FTEs performing pre-review
- 1 FTE physician

Inefficiency

- 250 to 350 duplicate sponsor generated reports daily
- 70% of site-generated reports classified as “not-related”
- IRB lacks details of subject involvement in multi-center trials
- Many sponsors do not analyze the significance

Lack of IRB Input

- **The problem and remedy are usually presented without prior IRB notice**
- **Lack of early IRB notification leads to delayed and less coordinated subject notice**

What Role for IRB?

- **Recommend requiring DSMBs for multi-center research**
- **IRBs evaluate DSMB findings and recommendations and determine process for subject notice and research changes needed**

What Role for IRB?

- **An entity independent of investigator must evaluate all adverse events in single-site trials**
 - By Sponsor, if applicable, or
 - By IRB
- **Review ALL adverse events, not just unanticipated and serious**

What AEs Should IRBs Review?

- **Broaden reporting to include all events that significantly impact a subject's quality of life**
- **Include events occurring before study agent use, e.g. during placebo run-in**

How to Report Information

- **DSMB reports with data, conclusions and recommendations**
- **Aggregated data of little value**
- **Details required from single-sites**
- **Standard report formatting**