

# Children's Hospital Institutional Review Board

## Information Sheet

### Adverse Events Reporting

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In order to fulfill its responsibilities to the United States Food and Drug Administration (FDA) and to the Department of Health and Human Services (DHHS), the IRB must receive and review information about adverse events experienced by research study participants. Based on the reports, the IRB may need to reassess the risk/benefit ratio and require consent form revisions. For reporting purposes, adverse events may be categorized as follows:

#### **Expected Adverse Events**

Adverse events that may be reasonably expected to arise as a result of research procedures are reviewed by the IRB and described in the consent form. When the study is submitted to the IRB for renewal, the incidence of these expected adverse events should be reported. Expected adverse events do not need to be reported to the IRB on an individual basis **unless, in the course of conducting the study, investigators notice that the expected adverse effects are occurring with greater frequency than anticipated, or at a higher level of severity than expected.**

#### **Unexpected Adverse Events**

During the study's approval period, investigators should report to the IRB any adverse event resulting from study procedures (either at Children's or at another institution) if the adverse event:

- Is unexpected (regardless of seriousness)
- Is more serious than expected
- Occurs more frequently than expected

Please refer to the Adverse Events Reporting Guidelines for details on the requirements and timelines for reporting adverse events.

[http://irb.seattlechildrens.org/forms/adverse\\_event\\_forms/AE\\_reporting\\_guidelines.doc](http://irb.seattlechildrens.org/forms/adverse_event_forms/AE_reporting_guidelines.doc)

The investigator provides information to the IRB on the event and how it was handled, the event's relationship to the study, i.e., unrelated, possible, probable or definitely attributable to the study, and the outcome. Report adverse events that occur in participants enrolled under Children's IRB approval on Children's Adverse Event Report Form.

[http://irb.seattlechildrens.org/forms/adverse\\_event\\_forms/AE\\_event\\_report.doc](http://irb.seattlechildrens.org/forms/adverse_event_forms/AE_event_report.doc)

The IRB reviews this information to determine if the study should be modified to reduce the risks, or if the consent form should be revised to include the unanticipated adverse effect.

Please note that it is probably better to over-report than to under-report. In some instances, adverse events that do not fit into any of the above categories should be reported to the IRB, e.g., events requiring treatment, or events about which a subject is upset.