Adverse Event Tracking Log

Adverse events are "any untoward or unfavorable medical occurrence in a human subject including any abnormal sign, symptom or disease,...whether or not associated with the subject's participation in the research". **Internal** adverse events that are **unexpected** and **related/possibly related** to the research and **external** adverse events that are **serious, unexpected and related/possibly related** must be reported to the IRB within 5 working days/7 calendar days of the date the investigator first become aware of them. Adverse events that are **expected** i.e., documented in the protocol are not reported to the IRB. For investigator-monitored studies a cumulative report of all adverse events must be submitted at continuing review.

Instructions: This log facilitates tracking and timely reporting of all applicable adverse events according to **PHRC Reporting Unanticipated Problems including Adverse Events policy**: http://healthcare.partners.org/phsirb/Guidance/Reporting_Unanticipated_Problems_including_Adverse_Events.1.11.pdf. A key for recording adverse event data is attached to this log. **NOTE: Entries in the log must be typed.**

Investigator:	
Study Title:	
Protocol #:	

Subject ID	Date of Adverse Event	Description of Event	Location	Severity	Expectedness	Relatedness	Requires Changes /Corrective Action	Date Reported To PHRC, If Applicable