

Appendix D
Guidance and Reporting Timelines for Reportable Events

Reportable Event	Anticipated	Unanticipated	Related <u>OR</u> Unknown	Unrelated	Report Promptly to IRB	Report to IRB at Continuing Review
Deaths	Yes		Yes		Yes-Within 5 business Days	Yes
Deaths	Yes			Yes	No-CR only	Yes
Deaths		Yes	Yes		Yes-Within 5 Business Days	Yes
Deaths		Yes		Yes	Yes-Within 5 Business Days	Yes
SAE	Yes		Yes		No-CR only	Yes
SAE	Yes			Yes	No-CR only	Yes
SAE		Yes	Yes		Yes-Within 5 Business Days	Yes
SAE		Yes		Yes	Yes-Within 5 Business Days	Yes
SP	Yes		Yes		No-CR only	Yes
SP	Yes			Yes	No	No
SP		Yes	Yes		Yes-Within 5 Business Days	Yes
SP		Yes		Yes	Yes-Within 5 Business Days	Yes
SP (DATA BREACH)*					*Yes-Within 1 hr. to PO/ISO/ACOS-R	Yes

This table is to provide general guidance and may not be applicable to all situations. Please seek assistance from the Research Administrative Officer or the Research Compliance Office if you are unsure of the reporting requirements for your specific situation.

*Requires reporting by telephone/email **within 1 hour** to PO/ISO/ACOS-R. See local policy "Reporting Research Information Incidents" for additional reporting information.