

Reportable Events Log

Reportable events: defined as events that are unanticipated and may cause risk of harm to the subject or others

There are many types of events that can fall under this requirement. In fact the most commonly known event – an adverse drug or device reaction – make up only a small portion of IRB reportable events.

An event can be an adverse drug or device reaction, a deviation from the protocol that caused harm to a subject or a violation that was intended to eliminate apparent or immediate harm to the subject. However, there are other events that the IRB needs to know about. Other types of events that should be reported to the IRB:

- Incarceration of an enrolled subject when your study was not approved to include prisoners,
- An unresolved subject complaint that indicates a potential increase or unexpected risk
- New information that presents a change to the risks or potential benefits.

A deviation or violation from the IRB approved protocol

Instructions: This log facilitates tracking and timely reporting of all applicable events deemed unanticipated, related, harmful and/or adverse.

Principle Investigator:								
Protocol Title:								
Protocol Number:								
Adverse Event Key	Location:	Internal = I		External (coordinating sites) = Ex				
	Severity:	Serious = S		Non-serious = N				
	Expectedness:	Expected = E		Unexpected = UE				
	Relatedness:	Related = R		Possibly Related = P			Unrelated = UR	
Subject ID	Date of Adverse Event	Description of Event	Location	Severity	Expectedness	Relatedness	Requires Changes/Corrective Action	Date Reported to NYUSoM IRB

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NOTES:
