Reportable Event Examples

The table below provides examples of common types of events that require or do not require reporting to the IRB. This list is NOT exhaustive and study teams should review the reportable events section of the Investigator Manual and the reportable events page of the IRBs website for detailed guidance.

REPORTABLE EVENT EXAMPLE	REPORT EVENT CATEGORY
• **Dosing errors of ANY kind (under dosing/over dosing)** • **50mL of blood was collected instead of the protocol approved 5mL** • Missing collection of research saliva samples from 15 subjects	**NONCOMPLIANCE**
A lab test, being run for subject safety reasons, was missed (e.g., a liver panel on a drug known to cause liver toxicity)	**NONCOMPLIANCE**
(*Occurs on a multi-site study for which UW is the IRB of record for two additional sites: MCW and Stanford*) Stanford sent identifiable information to UW; when the protocol says the data shared will be de-identified.	**NONCOMPLIANCE** *(Any event, that meets UW reporting requirements, which occurs at another site that has ceded review to UW; should be reported to the UW IRB)*
Study subjects are experiencing more severe nausea while taking the investigational drug than what was previously expected	**UNANTICIPATED PROBLEM**
12 study subjects at 4 different institutions (including 3 at UW) have experienced seizures while on study drug. This was not a previously known risk of the study drug.	**UNANTICIPATED PROBLEM**
Incarceration of a subject while they are enrolled on a research study.	**UNANTICIPATED PROBLEM**
An action letter describing forthcoming risk updates to the consent form was received. The sponsor does not know when the changes will be available for submission to the IRB.	**NEW INFORMATION**
An incidental finding of clinical significance was seen on a research scan. The protocol does not currently have a plan for disclosure of clinically significant findings.	**NEW INFORMATION**
Study enrollment was halted earlier than expected due to funding issues	**NEW INFORMATION**
The PI for the study is on medical leave for 2 months	**NEW INFORMATION**
A **single** incident of a study subject signing an **un-stamped** (but currently approved version) of the consent form	**DOES NOT REQUIRE REPORTING** (see Investigator Manual)
On **one** occasion, the study team failed to perform a motor-function test on a subject (this was **not** being done for safety purposes)	**DOES NOT REQUIRE REPORTING** (see Investigator Manual)
A one-time event of a single **study subject** failing to complete a research questionnaire (i.e., an incident of SUBJECT noncompliance)	**DOES NOT REQUIRE REPORTING** (see Investigator Manual)