

OHRs Information Sheet Adverse Event Ranking Scale

<i>PSU Rank</i>	<i>Reviewer's Assessment*</i>
0	This is an anticipated risk , whether related or unrelated to the investigational procedures (e.g., related to the subject's concurrent conditions OR described in the consent form and not indicative of unacceptable frequency or unusual concern).
1	The event is not related to the investigational procedures (to reasonable level of likelihood).
2A	For a multicenter trial (AE occurring at external site and/or on a related protocol) - There is insufficient data to conclude that a "reasonably foreseeable" risk exists.
2B	Local event - There is insufficient data to conclude that a "reasonably foreseeable" risk exists.
3	The event is of unusual concern (it would otherwise be of Rank 0, 1 or 2).
4	A new " reasonably foreseeable " risk is believed to exist.†
5	Probable imminent danger to subjects

* This is the IRB *reviewer's* assessment, which often may differ from the investigator's assessment listed on the adverse event report.

† Generally, this grade is not assigned unless the following data are known:

- a. The "numerator" (number of similar reports); and
- b. At least 1 other similar event has been reported; and
- c. The "denominator" (number of subjects who have received the investigational item or who have enrolled in the study). Note: the denominator may not be needed, if event is distinguishable from the underlying disease or from the known side effects of other drugs or therapies that the subject was receiving.