

DDM-8 Appendix B

Appendix B Adverse Event Attributions

Documentation of attribution of an adverse event will be based on what the sponsor or IRB requires. Some sponsors may use a 5 option approach or a dichotomized approach (see below). The IRB uses a dichotomized approach of being related or not to the research. Default to the more stringent requirement.

Dichotomized Approach		5 Option Approach	
Attribution	Definition	Attribution	Definition
Related	Reasonable causal relationship between the AE and the intervention/research.	Definite	AE clearly related to the intervention/research.
		Probable	Likely related to the intervention/research.
		Possible	May be related to the intervention/research.
Unrelated	No reasonable causal relationship between the AE and the intervention/research.	Unlikely	Doubtfully related to the intervention/research.
		Unrelated	Clearly not related to the intervention/research.