

Example Risk Register

Identify	Analyse		Rank	Monitor		Act
← PLAN →		← DO & CHECK →				RESPOND
Risk	Probability	Impact	Level of Risk (Probability + Impact)	Mitigation Approach	Frequency & Type of Monitoring	Status
<p>Risks that will impact participant safety or reliability of data</p> <p><i>Remember to differentiate between cause of risk actual risk consequence of risk.</i></p>	<p style="color: red;">High</p> <p style="color: orange;">Moderate</p> <p style="color: green;">Low</p> <p>Risk Appetite or Threshold</p>	<p style="color: red;">High</p> <p style="color: orange;">Moderate</p> <p style="color: green;">Low</p> <p>If the risk actually occurred, how big would the impact be?</p>	<p style="color: red;">Critical</p> <p style="color: red;">High</p> <p style="color: orange;">Moderate</p> <p style="color: green;">Low</p> <p>Critical = CAPA required High + High = Critical Moderate + High = High Low + Moderate = Mod</p>	<p>What new task or processes do you need to create to help mitigate the impact? This may include SOP's, training strategies, new equipment, policies, etc</p>	<p>What plan will you implement to manage the ongoing review of your mitigation approach? Who will be responsible?</p>	<ol style="list-style-type: none"> 1. CAPA completed? Y/N/NA 2. Mitigation plan adapted as required in response to CAPA? 3. Responsibility delegated? 4. Resolved or Ongoing?
1						
2						
3						