Reportable Event Guidance for Board Members

1. Does the event constitute **an unanticipated problem involving risks to subjects or others**?

Unanticipated problem*	1. is **unforeseen,** 2. **suggests** that research places **subjects at greater risk than was previously known** or recognized, AND 3. is **related** or **possibly related to** a subject's **participation in research**

*All three criteria must be met

Unforeseen:
- The event is "unexpected"
  - Not reflected in the protocol-related documents (such as the IRB-approved research protocol, the investigator's brochure/package insert, the device investigational plan, or the current IRB–approved informed consent document); OR
  - Not accurately reflected in the protocol related documents; OR
  - Occurring at greater severity; OR
  - Occurring at greater frequency; OR
  - Otherwise unforeseeable given the research procedures and characteristics of the study population.

Subjects at greater risk than was previously known
- May alter the risk-benefit ratio; OR
- May require changes to the protocol-related documents; OR
  - Have changes been proposed or submitted?
- May require additional monitoring to mitigate the risk
  - Have changes been proposed or submitted?

Related / possibly related to participation
- It is probable that a causal relationship exists between the event and some aspect of research participation; OR
- Event is categorized as possibly, probably, or definitely related; OR
- There is a > 50% chance that the event was caused by a subject's participation in research.

2. Is any of the following warranted?
   - Modification to the consent form or the consent process
   - Reconsenting active or non-active participants
   - Modification to the protocol
   - Increased monitoring
   - Arrangements for clinical care outside of the research or additional follow up
   - Notifying other sites
   - Earlier continuing review, suspension, or termination of the research

Board Recommendations ***This is a 3 part decision to be made when the board has completed the review of an action item.***	
Part 1: Decisions regarding unanticipated problem determination	
• **Unanticipated problem**	Yes or No If yes, the event is reportable
Part 2: Decisions regarding event	
• Accept • Accept pending responses (additional information needed) • Require earlier continuing review • Suspension or termination of the research	