


**Protocol Deviations:
How to Avoid the Muddy water**

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Goal

Think about how the information you hear
might apply to your role and help you
conduct your research


IE: Safety, Data, Compliance, Financials



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What is a Protocol Deviation?

- Any variation from the approved protocol
 - Preventable
 - Can put subjects at ↑ risk
 - Frequently not recognized and reported



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Types of Protocol Deviations

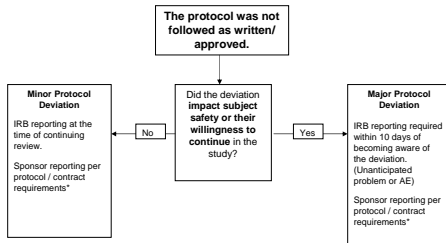
- Minor
- Major
- Planned
- *** Deviations necessary to eliminate apparent or immediate hazards to a subject(s)

What to Do??



- Think subject safety / accountability
- Develop/ define a preventative action
- Consider reporting requirements
- Call with any ?s

PROTOCOL DEVIATION DECISION TREE



*Sponsor and IRB reporting are typically not the same.
**Planned protocol deviations MUST be approved by the sponsor AND IRB in advance.
