

FlowChart for When and How to Report Deviations, Violations, and Single Subject Exception Requests

I?@1 01<->A>1 2; 9 <> @ /; 8A: 01 f? /; : @ 8

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1 3 8. B 8A1?; A@ 2>: 31 1@

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1 3 ?/410A5 5@9 5?10 - <<

f?@1 01/55: @ 01<->A>1 2; 9 <> @ /; 8
5 @: 010@ >10A/1 >57@ @1 ?A. 6/@

) 58?A. 6/@ >34@ >C12 >1. 1 ; >
-OB1>?1E - 21/@0. 01<->A>1 2; 9 @

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" 5@1 ; !

Depart, then report to the IRB within 10 working days using the Protocol Deviation/Violation Form*

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Submit the Single Subject Exception Request Form and obtain IRB approval before departure

Report to the IRB within 10 working days using the Protocol Deviation/Violation Form*