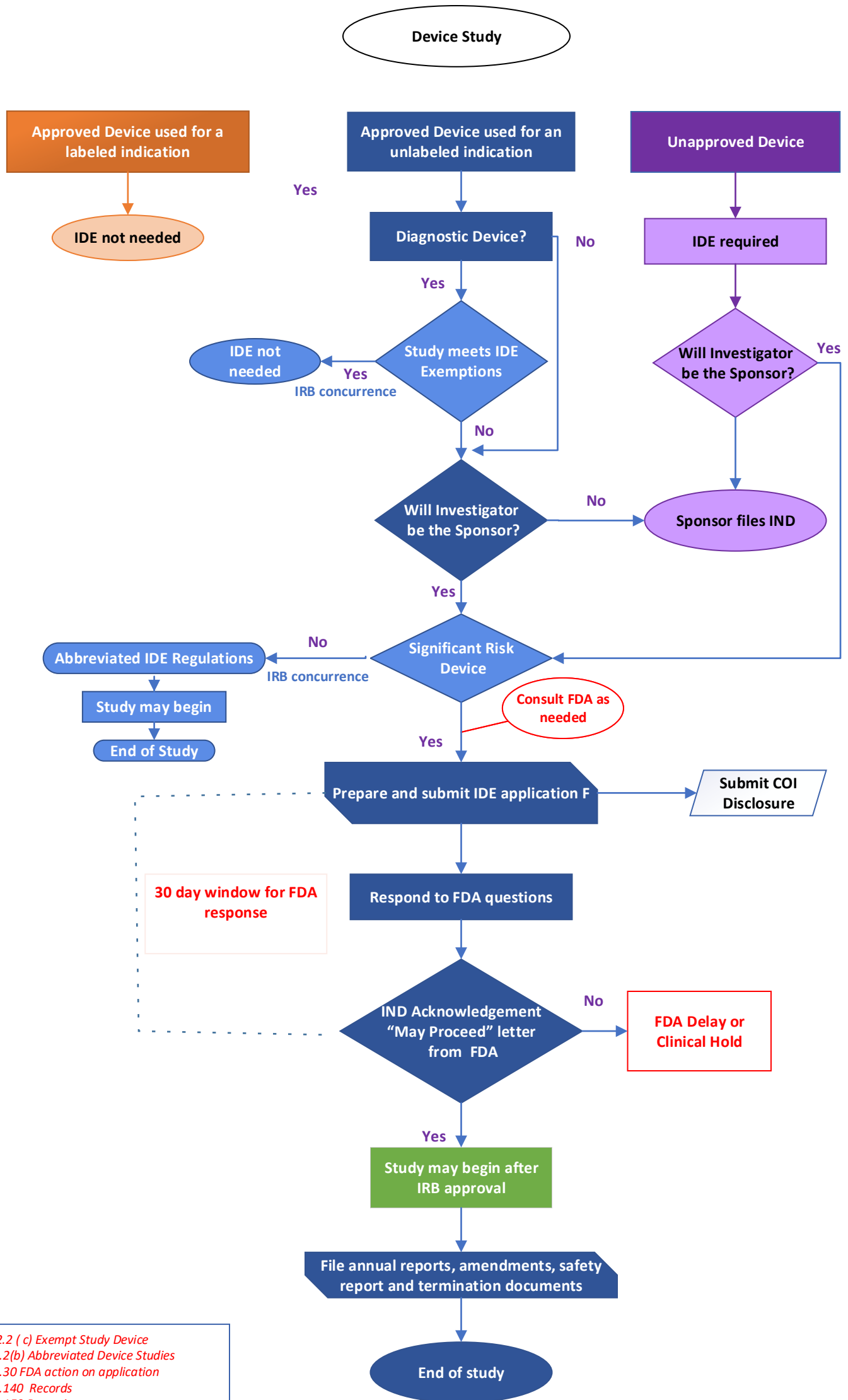


# Sponsor / Investigator IDE Flowchart for Proposed Device Study



812.2 (c) Exempt Study Device  
 812.2(b) Abbreviated Device Studies  
 812.30 FDA action on application  
 812.140 Records  
 812.150 Reporting  
 812.40 Responsibilities of Sponsor  
 812.100 Responsibilities of Investigators