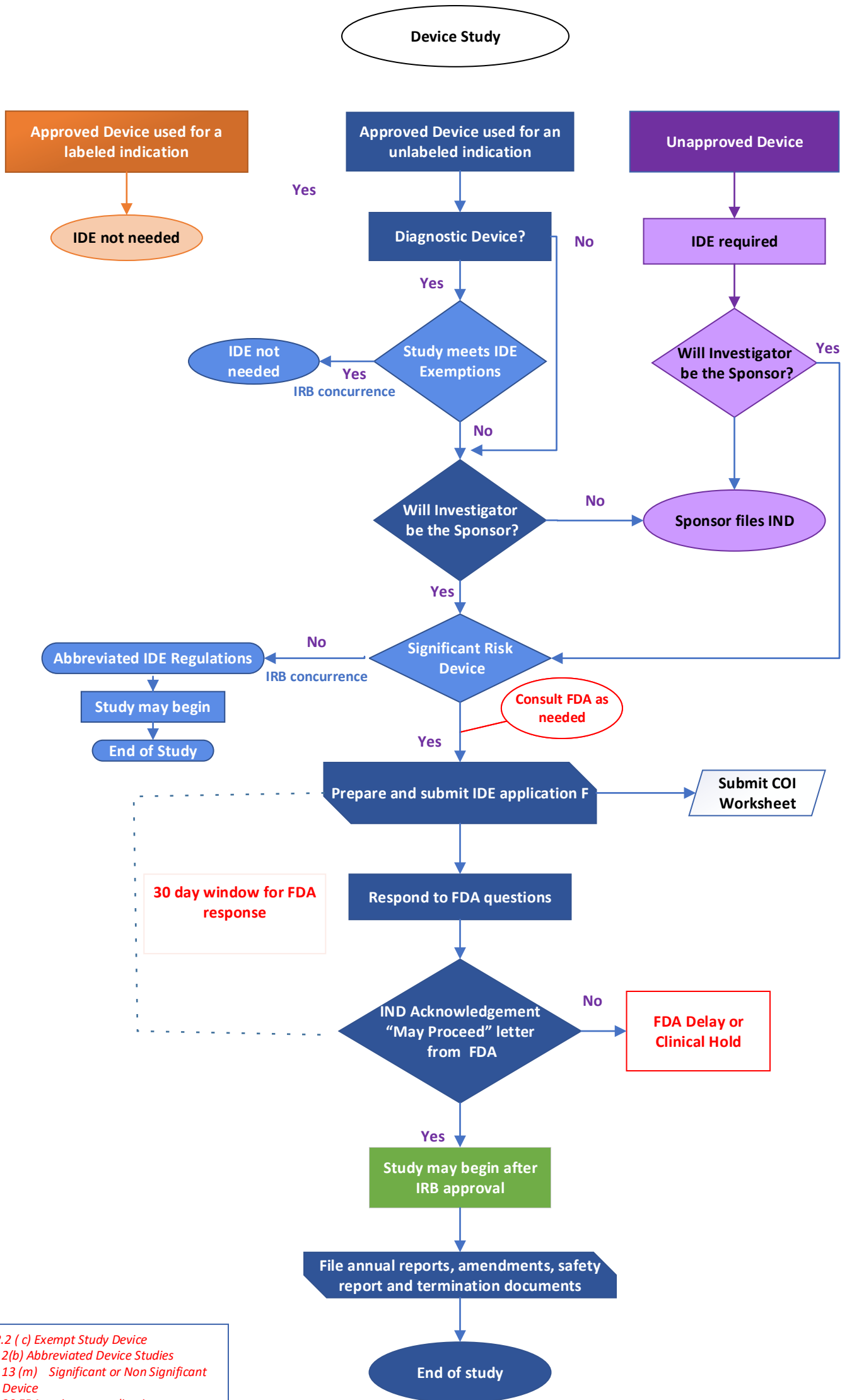


Sponsor / Investigator IDE Flowchart for Proposed Device Study



- 812.2 (c) Exempt Study Device
- 812.2(b) Abbreviated Device Studies
- 812.13 (m) Significant or Non Significant Risk Device
- 812.30 FDA action on application
- 812.140 Records
- 812.150 Reporting
- 812.40 Responsibilities of Sponsor
- 812.100 Responsibilities of Investigators