ITHS
Institute of Translational Health Sciences

Does an Investigator-Initiated Device Study Require an IDE?

Exempt study → First, identify if the use of the device for this study is exempt from the requirement for an IDE at 21 CFR 812.2(c)1-7 → **No IDE**

Significant Risk(SR) Study → If the device study is not exempt, then evaluate the risk of the device in the study. Determine if the device study meets the criteria of a significant risk device study at 21 CFR 812.3. → **Submit IDE to FDA**

Non-Significant Risk (NSR) Study → If the device study does not meet the criteria for a SR device, then it is a non-significant risk (NSR) study. Obtain IRB approval and meet the abbreviated requirements at 21 CFR 812.2(b). → **No IDE with the FDA (Abbreviated IDE)**