Does the protocol assess a device’s ability to (or safety in) diagnose, predict, or treat a disease process or other condition, or affect structure or function of the body?

**YES**

**Yes:** safety or effectiveness data are collected on the medical device

Does the use of the device meet a criterion for exemption from the IDE regulations?

**NO**

**IDE Regs apply; study is FDA-regulated**

IRB makes SR vs. NSR device study determination

**SR**

FDA must approve the IDE

**NSR**

IDE is approved; investigator must follow abbreviated IDE regs [812.2 (b)]

**YES**

Will data be submitted to FDA as part of the development or marketing application of the device?

**NO**

**IDE Regs do not apply**

IRB must consider risks of device and device use for subject safety and minimization of study risks

*Note: if results will be submitted to FDA, study is still FDA-regulated and informed consent can not be waived (although informed consent enforcement discretion possible if anonymized leftover samples used)