Drugs are simple. They don't change during a trial, there is one primary route to market, there are recognized phases of testing, and there is lots of boilerplate for protocols. Devices are not simple. There are multiple routes to market. The device changes often. There are categories of investigational devices. Many companies are tiny and cannot afford expert help.

The following is the simplest possible primer on devices. Many nuances and technicalities are lost in the simplification.

WHAT IS A DEVICE?

In simple terms, it is a product used for a medical purpose that does not interact chemically or metabolically with the body. Beyond this, there are multiple nuances.

HOW DO DEVICES GET TO MARKET?

A. Modification
Ajax has FDA clearance for and makes a big and a small scalpel. They want to make a gigantic scalpel and market it. They can do this. FDA has an algorithm for deciding if using this route is possible.

B. 510K – Substantial Equivalence
A section in the original device law, section 510K, provided a new route. Congress said that if one device is on the market, another can say, "we are substantially equivalent to that device and you let that device on the market so we want the same rights too." The application to FDA is a 510K application. Clinical information is not mandatory but may be gathered or may be requested.

C. PMA – PreMarket Application
This is akin to an NDA; an application is made to FDA giving specific required information, the information is reviewed and may go to an advisory panel.

D. Reclassification
Devices are classified as I (simple devices), II (devices needing more controls to be marketed), or III. All devices that are new and novel are automatically Class III. The sponsor can apply to have the device re-classified.

3.5.2 DEVICES

HOW CAN DEVICES BE STUDIED PRIOR TO FDA CLEARANCE?

No drug or device may be shipped in interstate commerce unless it is cleared by FDA. How then, can a device be shipped for a study before it is cleared? An exception can be made to this rule; an Investigational Device Exemption or IDE.

WHAT ARE THE INVESTIGATIONAL DEVICE EXEMPTION CATEGORIES?

A. Full IDE
This is the equivalent of an IND. It is granted by FDA. Any device found to be a significant risk device must have the full IDE clearance.

B. Abbreviated IDE
Because there is a huge range of devices some with very trivial risk, Congress allowed some devices to be shipped with only an Abbreviated IDE. Seven elements must be met. These are found in 21 CFR 812.2. Item (b) reads…

"Obtains IRB approval of the investigation after presenting the reviewing IRB with a brief explanation of why the device is not a significant risk device, and maintains such approval;"

C. Exempt from IDE

A few devices are exempt from the need for an exemption (!) The exemption used most commonly is that for a diagnostic device if it is labeled

(i) Is noninvasive,

(ii) Does not require an invasive sampling procedure that presents significant risk,

(iii) Does not by design or intention introduce energy into a subject, and

(iv) Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

IS IRB REVIEW A REQUIREMENT?

IRB review is required for all clinical trials. Whether the route to market is a minor modification and the device is exempt from IDE does not matter. To decide if IRB review is required, use the applicability section of 21 CFR 56. The IRB and the device regulations are totally separate.

IS INFORMED CONSENT A REQURIEMENT?

Informed consent is required for all involvement of human subjects whether or not an IRB is involved. (See section 3.4) After all, wouldn't you rather know you were a subject?