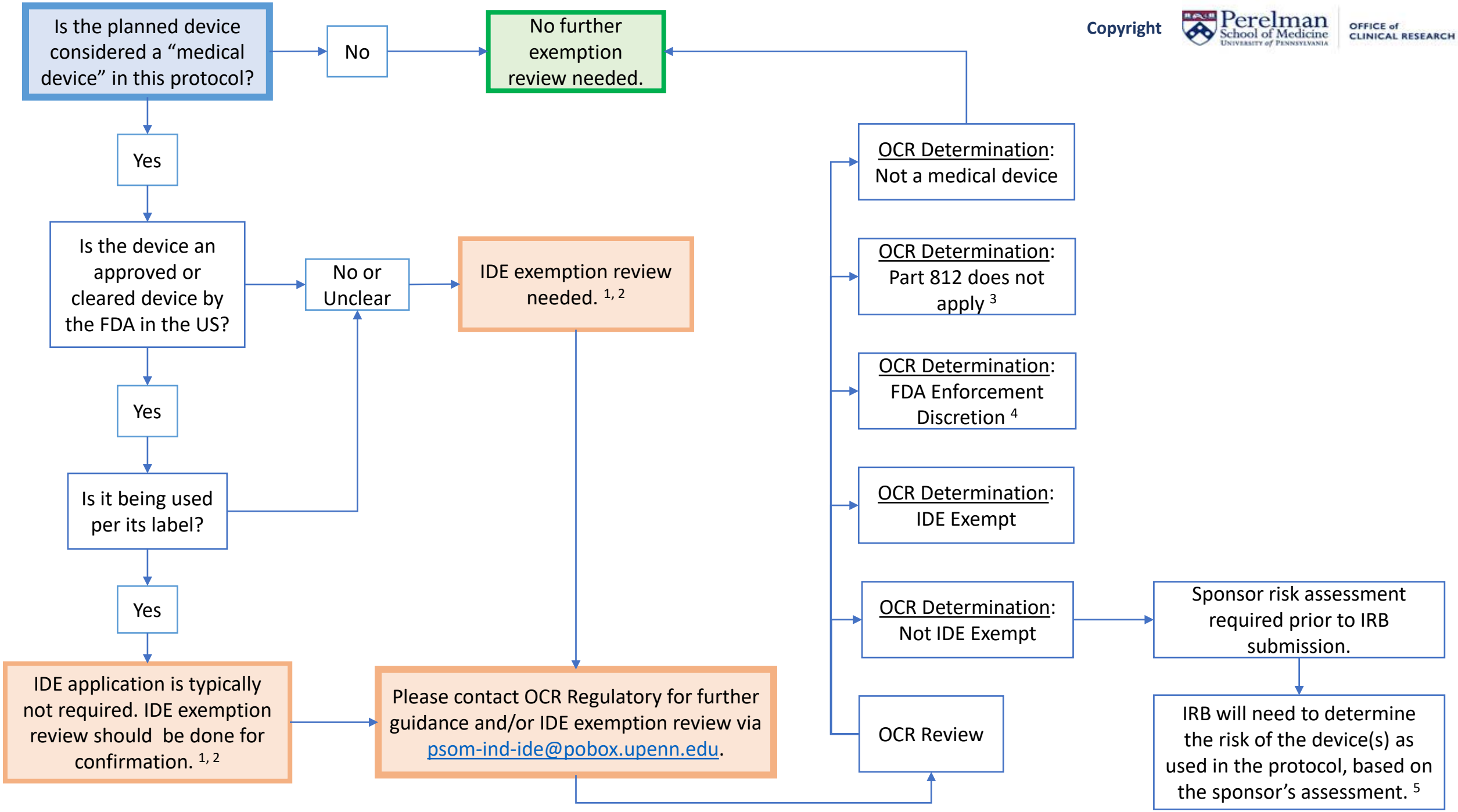

Footnotes

1. Penn investigators are not permitted to self-exempt from IDE regulations.
2. UPenn IRB Exemption from IDE Regulation guidance is available.
3. 21 CFR 812 (Investigational Device Exemptions) applies to "all clinical investigations of devices to determine safety and effectiveness…" (21 CFR 812.2(a). The FDA has further clarified that an IDE is not necessary for research investigating a physiological principle, with no intent of developing the device for marketing, and only using the device to address the research question. Therefore, the device would not be subject to Part 812 regulations if the following are true:
   a. The device is not being used in this research to determine its safety and/or effectiveness;
   b. The device is not being developed for marketing; and
   c. The research is investigating a physiological principle.
4. The device may meet the FDA definition of a medical device; however, at this time the FDA is not enforcing medical device regulations. Please see the following for: Examples of Software Functions for Which the FDA Will Exercise Enforcement Discretion.
5. The type of application (full or abbreviated) depends on the determined risk of the device in the trial. The Sponsor is responsible for making the initial risk determination based on the proposed use of a device in the study. A thorough discussion of how to make risk determinations for devices is available from the FDA guidance on medical device studies. The IRB then makes its own determination of risk based on the information provided by the Sponsor. More information on this can be found here.