Decision Trees for Investigational Device Studies[1]

Device studies are categorized into three types according to the Investigational Device Exemption regulations at 21 CFR 812:

- Exempt studies – these studies are exempt from the requirements of 21 CFR Part 812. Examples of exempt studies include: consumer preference testing, testing of a device modification, and diagnostic device studies (e.g., in vitro diagnostic studies). Visit the links below for additional information.
- Nonsignificant risk (NSR) device studies – these studies must meet the abbreviated IDE requirements at 21 CFR 812.2(b). Refer to the FDA Information Sheet Guidance "Significant Risk and Nonsignificant Risk Medical Device Studies" (linked below) for specific examples of NSR device studies.
- Significant risk (SR) device studies – these studies require an approved IDE (Investigational Device Exemption) from the FDA and must comply with the regulations at 21 CFR 812. Refer to the FDA Information Sheet Guidance "Significant Risk and Nonsignificant Risk Medical Device Studies" (linked below) for specific examples of SR device studies.

You may need to acquire additional information and/or documentation from the study sponsor or the FDA to submit to the IRB, depending on what type of device study you have. The decision trees below will help you determine whether you (A) have a device study, (B) whether FDA regulations apply to your study, (C) whether your study is exempt from IDE regulations and (D) what risk category your study falls into.

If you have questions, please contact OPHS at ophs@berkeley.edu.

FDA Information Sheet Guidance:

Frequently Asked Questions About Medical Devices

Significant Risk and Nonsignificant Risk Medical Device Studies

Link to FDA regulations:

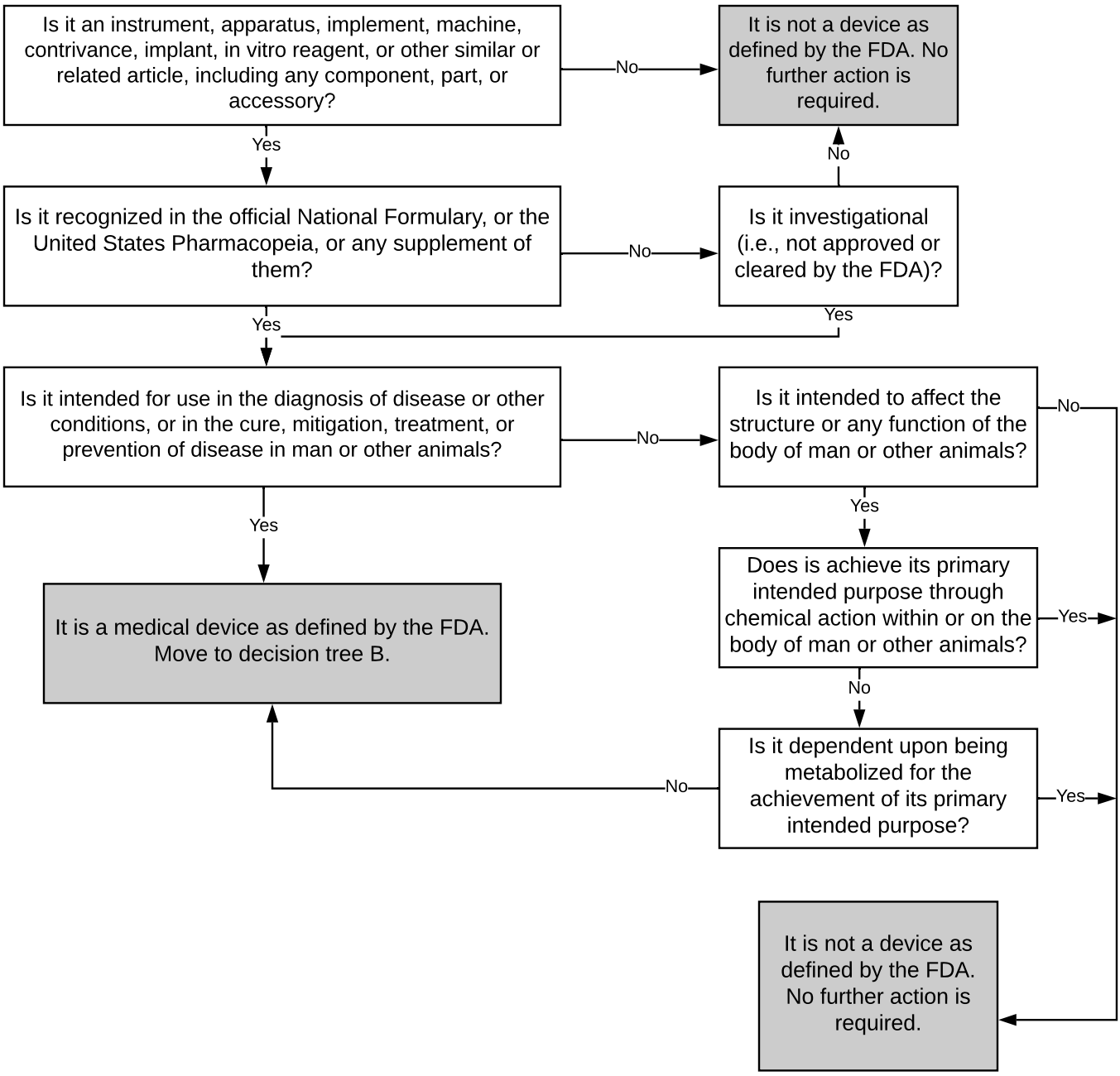
21 CFR Part 812

UCB Resources:

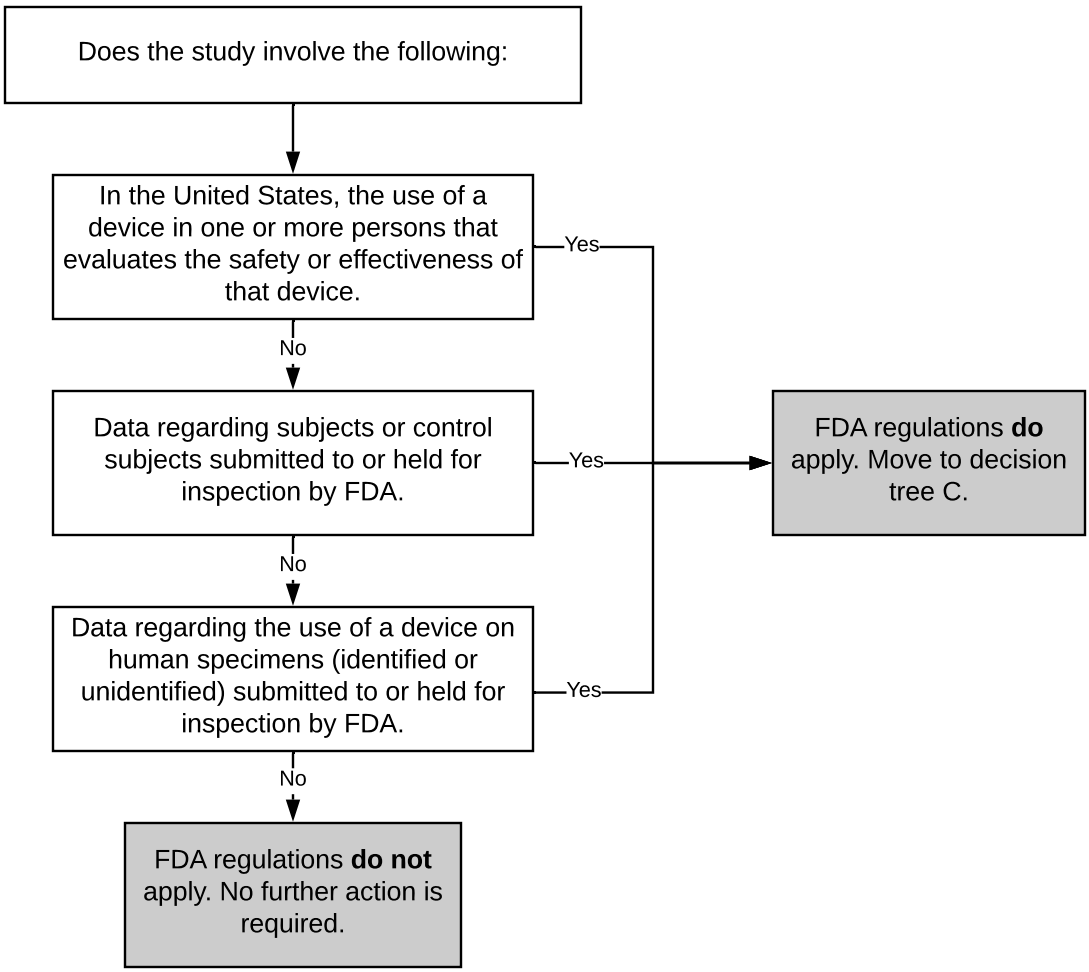
FDA-Regulated Research

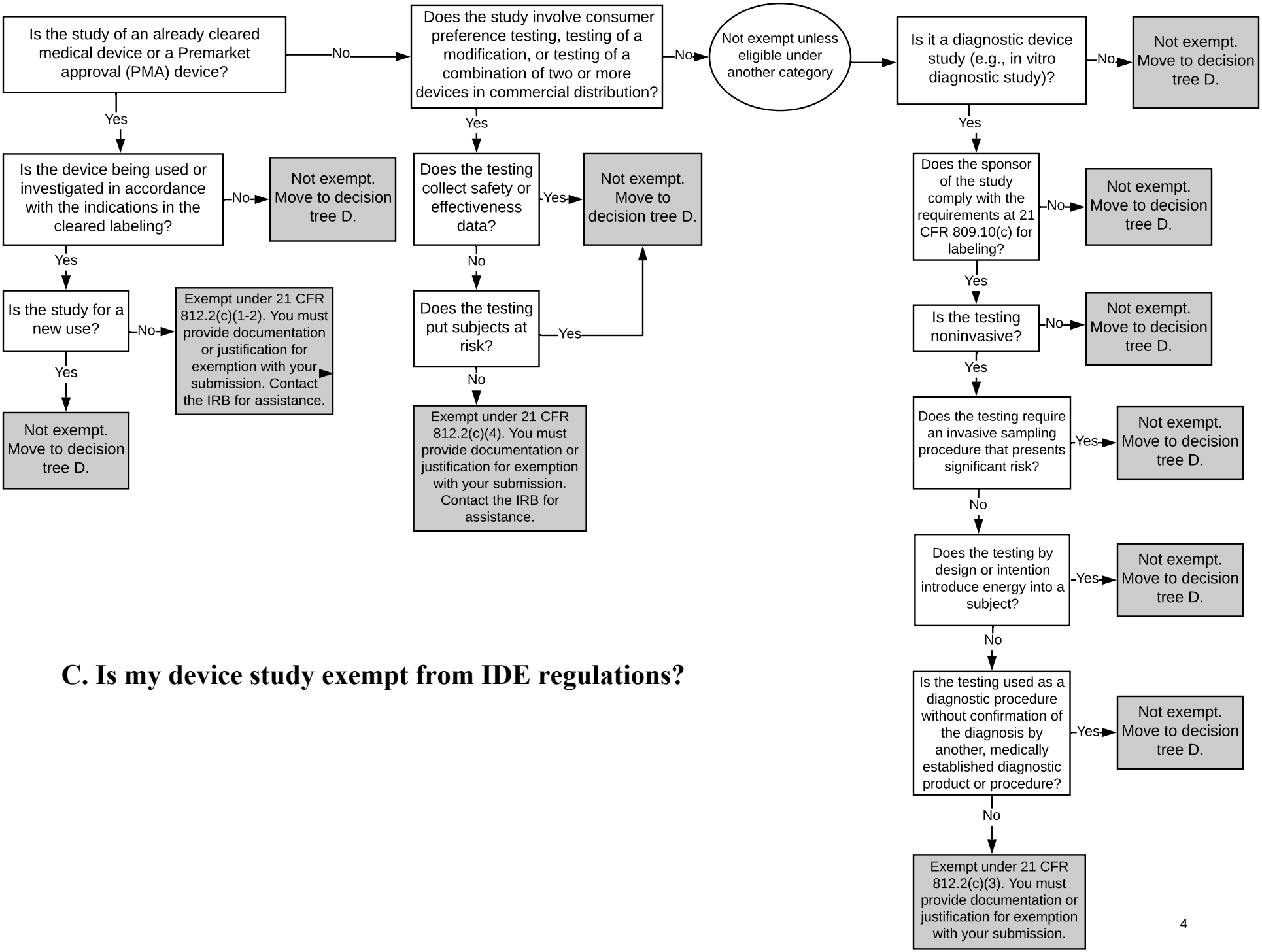
[1]This document is adapted from University of Colorado, Boulder's Guidance on Investigational Device Studies.

A. Do I have a medical device?



B. Do FDA regulations apply to my device study?





C. Is my device study exempt from IDE regulations?

D. Is my device study classified as SR or NSR?