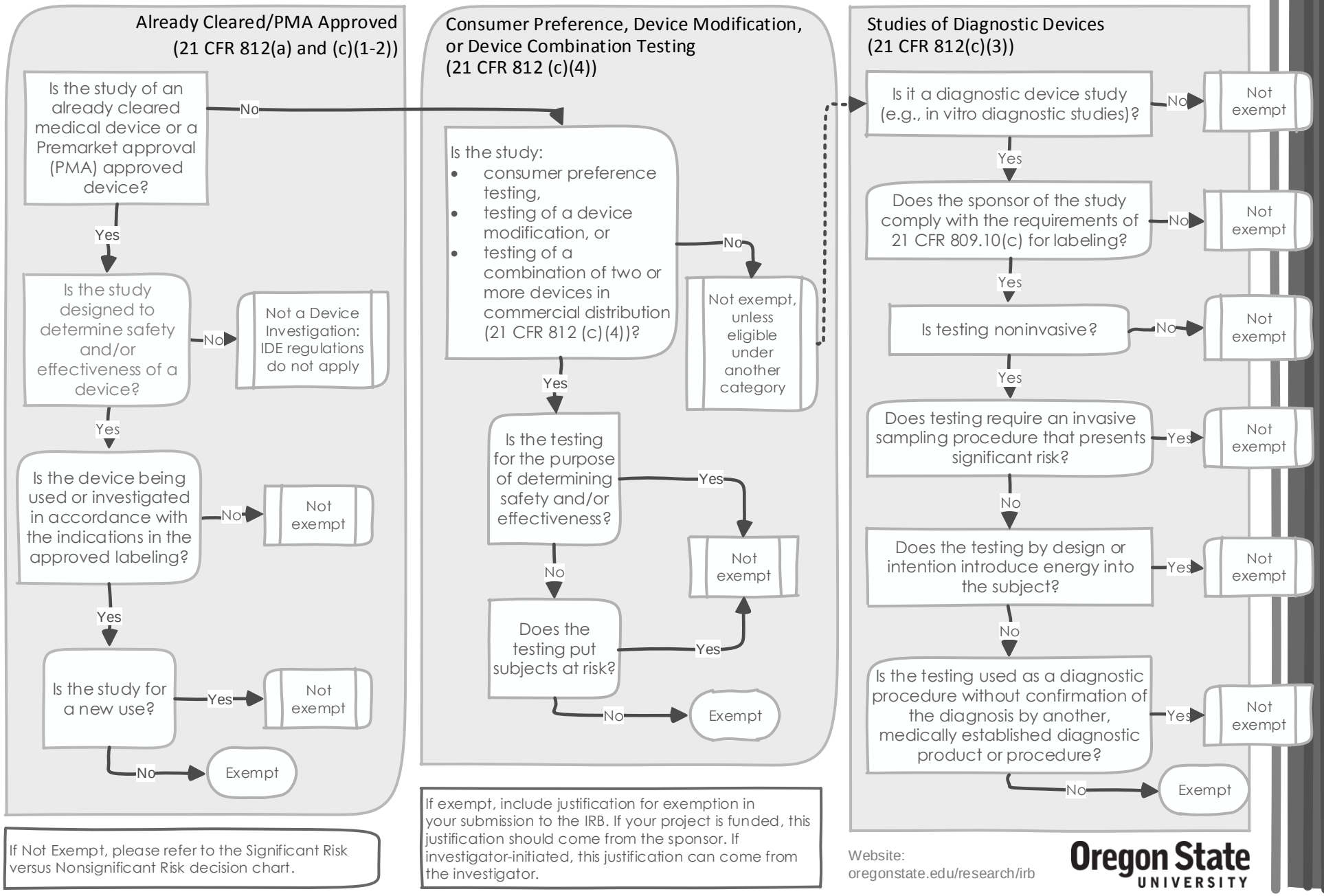
Is my Medical Device Study Classified as Exempt according to the Investigational Device Exemptions (IDE) Regulation (21 CFR 812)?

Exempt device studies are exempt from some (21 CFR 812), but not all, regulations (e.g. 21 CFR 50, 21 CFR 56).

This document is intended to be guidance only and cannot replace a formal determination from the FDA.



If Not Exempt, please refer to the Significant Risk versus Nonsignificant Risk decision chart.

If exempt, include justification for exemption in your submission to the IRB. If your project is funded, this justification should come from the sponsor. If investigator-initiated, this justification can come from the investigator.

Website:
oregonstate.edu/research/irb

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