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).

- **Already Cleared/PMA Approved (21 CFR 812(a) and (c)(1-2))**
  - Is the study of an already cleared medical device or a Premarket approval (PMA) approved device?
    - Yes: Exempt
    - No: Is the study designed to determine safety and/or effectiveness of a device?
      - Yes: Not a Device Investigation: IDE regulations do not apply
      - No: Is the device being used or investigated in accordance with the indications in the approved labeling?
        - Yes: Exempt
        - No: Is the study for a new use?
          - Yes: Not exempt
          - No: Exempt

- **Consumer Preference, Device Modification, or Device Combination Testing (21 CFR 812 (c)(4))**
  - Is the testing for the purpose of determining safety and/or effectiveness of a device?
    - Yes: Not exempt, unless eligible under another category
    - No: Is the testing put subjects at risk?
      - Yes: Exempt
      - No: Does the testing require an invasive sampling procedure that presents significant risk?
        - Yes: Not exempt
        - No: Does the testing by design or intention introduce energy into the subject?
          - Yes: Not exempt
          - No: Is the testing used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure?
            - Yes: Not exempt
            - No: Exempt

- **Studies of Diagnostic Devices (21 CFR 812(c)(3))**
  - Is it a diagnostic device study (e.g., in vitro diagnostic studies)?
    - Yes: Not exempt
    - No: Does the sponsor of the study comply with the requirements of 21 CFR 809.10(c) for labeling?
      - Yes: Not exempt
      - No: Is testing noninvasive?
        - Yes: Not exempt
        - No: Does testing require an invasive sampling procedure that presents significant risk?
          - Yes: Not exempt
          - No: Does the testing by design or intention introduce energy into the subject?
            - Yes: Not exempt
            - No: Is the testing used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure?
              - Yes: Not exempt
              - No: Exempt

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