This guidance document is used to determine whether IDE requirements for FDA-regulated device research are met. (see Footnotes 1 and 2)

1. Special issue where 21 CFR §812 does not apply

1.1 The protocol does not evaluate the device(s) being used for safety or effectiveness (see Footnote 3)

2. IDE Requirements (One of the following must be true)

2.1 The IRB confirms that the protocol will be conducted under an valid IDE

2.1.1 The submission documents a valid IDE number provided by the sponsor, CRO, or FDA

2.2 The IRB confirms that the protocol meets the abbreviated IDE requirements/NSR device 21 CFR §812.2(a) (see Footnote 4)

2.2.1 The device is not a banned device

2.2.2 The submission includes a brief explanation of why the device is not a significant risk device

2.2.3 The IRB will decide whether the device is not a significant risk (see "REGULATORY GUIDE: Non-Significant Risk Device (HRP-313)"

2.3 The IRB confirms that the protocol is IDE exempt under one of the following categories:

2.3.1 Approved devices used as labeled

2.3.1.1 The device is not a transitional device (regulated by FDA as a drug)

2.3.1.2 The device is legally marketed based on one of the following:

- PMA approval (FDA Guidance: Frequently Asked Questions About Medical Devices)
- 510(k) clearance (21 CFR §812.2(c)(1)-(2))
- HDE (FDA Guidance: Humanitarian Device Exemption (HDE) Regulation: Questions and Answers)
- Class I exemption (21 CFR §§862-892)

2.3.1.3 The device was used or investigated in accordance with the indications in the approved labeling (PMA, 510(k), HDE) or is used or investigated in accordance with its Class I exemption category

2.3.2 21 CFR §812.2(c)(3) Diagnostic device (see Footnote 5)

2.3.2.1 The device is a diagnostic device

2.3.2.2 The testing is noninvasive

2.3.2.3 The testing does not require an invasive sampling procedure that presents significant risk

2.3.2.4 The testing does not by design or intention introduce energy into a subject

2.3.2.5 The testing is not used as a diagnostic procedure without confirmation of the detection by another, medically established diagnostic product or procedure

2.3.3 21 CFR §812.2(c)(4) Consumer preference testing

2.3.3.1 The device is undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution

2.3.3.2 The testing is not for the purpose of determining safety or effectiveness

2.3.3.3 The testing does not put subjects at risk

2.3.4 21 CFR §812.2(c)(7) Custom device

2.3.4.1 The device is a custom device (see Footnote 6)

2.3.4.2 The device is not being used to determine safety or effectiveness for commercial distribution

3. Notes

4. Footnotes

4.1 FDA does NOT consider some mobile medical applications to meet the definition of medical device. See "Guidance for Industry and Food and Drug Administration Staff: Mobile Medical Applications" for examples and additional information. http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf

4.2 Device means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is: FDC Sec. 201(g)

1 Recognized by the FDA as an approved device;
2 Intended for use in the diagnosis of disease or other conditions, in the cure, mitigation, treatment, or prevention of disease; or
3 Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

4.3 The clinical use of an HDE (either on label or off label) is also not subject to 21 CFR §812 provided the protocol does not evaluate the HDE for safety or effectiveness

4.4 Additional FDA criteria for sponsors:

- The sponsor will label the device in accordance with 21 CFR §812.5.
- The sponsor will comply with the requirements of 21 CFR §812.46 with respect to monitoring investigations.
- The sponsor will ensure that each investigator participating in an investigation of the device obtains from each subject under the investigator’s care, consent under 21 CFR 50 and documents it, unless documentation is waived.
- The sponsor will maintain the records required under 21 CFR §812.140(b) (4) and (5) and make the reports required under 21 CFR §812.150(b) (1) through (3) and (5) through (10).
- The sponsor will ensure that participating investigators maintain the records required by 21 CFR §812.140(a)(3)(i) and make the reports required under 21 CFR §812.150(a)(1), (2), (5), and (7).
- The sponsor will comply with the prohibitions in 21 CFR §812.7 against promotion and other practices.
4.5 Additional FDA criterion for sponsors: The sponsor will label the device in accordance with 21 CFR §809.10(c).

4.6 Custom device means a device that necessarily deviates from devices generally available or from an applicable performance standard or pre-market approval requirement in order to comply with the order of an individual physician or dentist; is not generally available to, or generally used by, other physicians or dentists; is not generally available in finished form for purchase or for dispensing upon prescription; is not offered for commercial distribution through labeling or advertising; and is intended for use by an individual patient named in the order of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice.