ID:	
Notes:	

Can research involving a device be approved?[1,2,3,4]

One of the following categories must be met:

Device

1. ☐ Clinical Use of an HDE Device
   - 1.1. ☐ The protocol uses a HUD in a manner that does NOT evaluate the device for safety or effectiveness[5]

     HDE#
2. ☐ Device With an IDE
   - 2.1. ☐ The protocol will be conducted under an IDE
   - 2.2. ☐ The submission documents an IDE number provided by the sponsor, CRO, or FDA[6]

     IDE#

3. ☐ Abbreviated IDE
   - 3.1. ☐ One of the following is true[7]:
     - 3.1.1. ○ The FDA has NOT determined the device to be NSR
     - 3.1.2. ○ The FDA has determined the device to be NSR
   - 3.2. ☐ The device is NOT banned[8]
   - 3.3. ☐ One of the following is true:
     - 3.3.1. ○ The device is NOT intended as an implant
     - 3.3.2. ○ Even though the device is intended as an implant, the device does NOT present a potential for serious risk to the health, safety, or welfare of a subject
   - 3.4. ☐ One of the following is true:
     - 3.4.1. ○ The device is NOT purported or represented to be for a use in supporting or sustaining human life
     - 3.4.2. ○ Even though the device is purported or represented to be for a use in supporting or sustaining human life, the device does NOT present a potential for serious risk to the health, safety, or welfare of a subject
   - 3.5. ☐ One of the following is true:
     - 3.5.1. ○ The device is NOT for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health
     - 3.5.2. ○ Even though the device is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health, the device does NOT present a potential for serious risk to the health, safety, or welfare of a subject
   - 3.6. ☐ The device does NOT otherwise present a potential for serious risk to the health, safety, or welfare of a subject
   - 3.7. ☐ One of the following is true:
     - 3.7.1. ○ The device is NOT an *in vitro* companion diagnostic device
     - 3.7.2. ○ The device is an *in vitro* companion diagnostic device
   - 3.8. ☐ *In vitro* companion diagnostic device:
     - 3.8.1. ☐ Use of the investigational test results will NOT lead to some trial subjects foregoing or delaying a treatment that is known to be effective.
     - 3.8.2. ☐ Use of the investigational test results will NOT expose trial subjects to safety risks (e.g., adverse events from the experimental therapy) that (in some “net” sense) exceed the risks encountered with control therapies or non-trial standard of care.
     - 3.8.3. ☐ Based on *a priori* information about the investigational therapy, it is unlikely that incorrect test results would degrade the safety or efficacy of subjects’ treatment.
     - 3.8.4. ☐ Specimen acquisition done for investigational testing and outside the standard of care does NOT require an invasive sampling procedure that presents significant risk.
   - 3.9. ☐ The submission includes a brief explanation that the device is NSR
   - 3.10. ☐ One of the following is true:
     - 3.10.1. ○ The convened IRB agrees with the sponsor's explanation that the device is NSR
     - 3.10.2. ○ The convened IRB has documented in writing its own rationale that the device is NSR
   - 3.11. ☐ One of the following is true:
     - 3.11.1. ○ The submission does NOT include the device packaging
     - 3.11.2. ○ The device packaging includes the statement "CAUTION--Investigational device. Limited by Federal (or United States) law to investigational use."

4. ☐ IDE Exempt: Approved Device Used as Labeled
   - 4.1. ☐ The device is NOT regulated by FDA as a drug ("transitional device")
   - 4.2. ☐ One of the following is true:
     - 4.2.1. ○ The device has PMA approval[3] PMA# _____
     - 4.2.2. ○ The device has 510(k) clearance[9] 510(k)# _____
     - 4.2.3. ○ The device has HDE approval[5] HDE# _____
     - 4.2.4. ○ The device is Class I/II exempt from pre-market notification requirements[10] Reg# _____
   - 4.3. ☐ The device is investigated in accordance with the indications in the approved labeling
   - 4.4. ☐ Evidence of FDA approval and FDA-approved indications is in the protocol file. (e.g., HDE letter, PMA letter, 510(k) letter, Class I/II exemption regulatory category)
5. ☐ IDE Exempt: Diagnostic Device
   - 5.1. ☐ The device is a diagnostic device
   - 5.2. ☐ The testing is noninvasive
   - 5.3. ☐ The testing does NOT require an invasive sampling procedure that presents significant risk
   - 5.4. ☐ The testing does NOT introduce energy into a subject
   - 5.5. ☐ The testing is NOT used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure[11]
6. ☐ IDE Exempt: Custom Device
   - 6.1. ☐ The device is a custom device[12]
   - 6.2. ☐ The device is NOT being used to determine safety or effectiveness for commercial distribution
7. ☐ IDE Exempt: Consumer Preference Testing
   - 7.1. ☐ The device is undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution
   - 7.2. ☐ The testing is NOT for the purpose of determining safety or effectiveness
   - 7.3. ☐ The testing does NOT put subjects at risk
8. ☐ Mobile Medical Application[13]
   - 8.1. ☐ The clinical investigation evaluates a device that is a "mobile medical application" that falls under FDA enforcement discretion
9. ☐ Low Risk General Wellness Device[14]
   - 9.1. ☐ The clinical investigation evaluates a device that is a "low risk general wellness device" that falls under FDA enforcement discretion
10. ☐ Combination Product[15]
    - 10.1. ☐ The clinical investigation is under an IND where FDA has designated the test article as combination product regulated as a drug
11. ☐ Real World Evidence[16]
    - 11.1. ☐ The research involves the administration of a legally-marketed device under the authority of a health care practitioner within a legitimate practitioner-patient relationship
    - 11.2. ☐ The process for gathering the data does not influence treatment decisions
12. ☐ Clinical Investigation Conducted Outside the United States[17]
    - 12.1. ☐ The research will be conducted outside the United States
    - 12.2. ☐ One of the following is true:
      - 12.2.1. ○ The sponsor does not intend to submit the data to FDA
      - 12.2.2. ○ The study will be conducted in accordance with good clinical practice (GCP)

Footnotes

1. In this checklist, "research" means <Research as Defined by FDA> involving <Human Subjects as Defined by FDA>, and "subject" means <Human Subject as Defined by FDA>.
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, or 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.
3. 21 CFR §812.2
4. FDA Guidance: Frequently Asked Questions About Medical Devices
5. FDA Guidance: Humanitarian Device Exemption (HDE) Regulation: Questions and Answers
6. Investigator brochures are not sufficient for documentation because they are not protocol-specific. Sponsor investigators require documentation from the FDA.
7. The convened IRB needs to make the determinations in section 3. 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 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.
8. See FDA List of Banned Devices
9. 21 CFR §812.2(c)(1)-(2)
10. See FDA List of Class I/II Exempt Devices
11. Additional FDA criterion for sponsors: The sponsor will label the device in accordance with 21 CFR §809.10(c).
12. 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.
13. Guidance for Industry and Food and Drug Administration Staff: Mobile Medical Applications
14. Guidance for Industry and Food and Drug Administration Staff: General Wellness: Policy for Low Risk Devices
15. Guidance for Industry and Food and Drug Administration Staff: In Vitro Companion Diagnostic Devices
16. Guidance for Industry and Food and Drug Administration Staff: Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices
17. Guidance for Industry and Food and Drug Administration Staff: Food and Drug Administration Acceptance of Foreign Clinical Studies Not Conducted Under an IND