**CHECKLIST: Devices**

<table>
<thead>
<tr>
<th>ID:</th>
<th>Notes:</th>
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<tbody>
<tr>
<td></td>
<td>Can research involving a device be approved? 1, 2, 3, 4</td>
</tr>
<tr>
<td></td>
<td>One of the following categories must be met:</td>
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1. [ ] Clinical Use of an HDE Device
   - [ ] 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
   - [ ] The protocol will be conducted under an IDE
   - [ ] The submission documents an IDE number provided by the sponsor, CRO, or FDA 8
     - IDE# |

3. [ ] Abbreviated IDE
   - [ ] One of the following is true 7.
     - 3.1. [ ] The FDA has NOT determined the device to be NSR
     - 3.2. [ ] The FDA has determined the device to be NSR

4. [ ] IDE Exempt: Approved Device Used as Labeled
   - [ ] The device is NOT regulated by FDA as a drug ("transitional device")
   - [ ] One of the following is true:
     - 4.2.1. [ ] The device has PMA approval 6
     - 4.2.2. [ ] The device has 510(k) clearance 9
     - 4.2.3. [ ] The device has HDE approval 5
     - 4.2.4. [ ] The device is Class III exempt from pre-market notification requirements 10
     - 4.2.5. [ ] The device is an Automatic Class III (De Novo) cleared device 11
   - [ ] The device is investigated in accordance with the indications in the approved labeling
   - [ ] Evidence of FDA approval and FDA-approved indications is in the protocol file. (e.g., HDE letter, PMA letter, 510(k) letter, Class III exemption regulatory category)
6. [ ] 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.

   Device

6. [ ] IDE Exempt: Custom Device
   5.1. [ ] The device is a custom device
   5.2. [ ] The device is NOT being used to determine safety or effectiveness for commercial distribution

   Device

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

   Device

8. [ ] Mobile Medical Application
   8.1. [ ] The clinical investigation evaluates a device that is a "mobile medical application" that falls under FDA enforcement discretion

   Device

9. [ ] Low Risk General Wellness Device
   9.1. [ ] The clinical investigation evaluates a device that is a "low risk general wellness device" that falls under FDA enforcement discretion

   Device

10. [ ] Combination Product
    10.1. [ ] The clinical investigation is under an IND where FDA has designated the test article as combination product regulated as a drug

    Device

11. [ ] Real World Evidence
    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

    Device

12. [ ] Clinical Investigation Conducted Outside the United States
    12.1. [ ] The research will be conducted outside the United States

   Device
### CHECKLIST: Devices

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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 §312.2
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 IRR needs to make the determinations in section 3. Additional FDA criteria for sponsors. The sponsor will label the device in accordance with 21 CFR §312.5. The sponsor will comply with the requirements of 21 CFR §312.46 with respect to monitoring investigations; The sponsor will maintain the records required under 21 CFR §312.140(b)(4) and (5) and make the reports required under 21 CFR §312.150(b)(1) through (3) and (6) through (10); The sponsor will ensure that participating investigators maintain the records required by 21 CFR §312.140(a)(3)(i) and make the reports required under 21 CFR §312.150(a) (1), (2), (6), and (7); The sponsor will comply with the prohibitions in 21 CFR §312.7 against promotion and other practices.
8. See FDA List of Handed Devices
9. 21 CFR §312.2(a)(1)-(2)
10. See FDA List of Class III Exempt Devices
11. De Nova Classification Request
12. Additional FDA criterion for sponsors: The sponsor will label the device in accordance with 21 CFR §312.5. The sponsor will comply with the requirements of 21 CFR §312.46 with respect to monitoring investigations; The sponsor will maintain the records required under 21 CFR §312.140(b)(4) and (5) and make the reports required under 21 CFR §312.150(b)(1) through (3) and (6) through (10); The sponsor will ensure that participating investigators maintain the records required by 21 CFR §312.140(a)(3)(i) and make the reports required under 21 CFR §312.150(a) (1), (2), (6), and (7); The sponsor will comply with the prohibitions in 21 CFR §312.7 against promotion and other practices.
13. Guidance for Industry and Food and Drug Administration Staff: Mobile Medical Applications
15. Guidance for Industry and Food and Drug Administration Staff: In Vitro Companion Diagnostics 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