|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Protocol Number: | Click or tap here to enter text. | Principal Investigator: | Click or tap here to enter text. | |
| Study Title: | Click or tap here to enter text. | | | |
| Completed By: | Click or tap here to enter text. | | Date: | Click or tap to enter a date. |

**Can research involving a device be approved?[[1]](#endnote-1) [[2]](#endnote-2) [[3]](#endnote-3) [[4]](#endnote-4)**

One of the following 12 highlighted categories must be met:

|  |  |
| --- | --- |
| Device: | Click or tap here to enter text. |

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]](#endnote-5) |
|  | HDE# | Click or tap here to enter text. |

2. Device With and IDE

|  |  |  |
| --- | --- | --- |
| 2.1 |  | The protocol will be conducted under an IDE |
| 2.2 |  | The submission documents include an IDE number provided by the sponsor, CRO, or FDA[[6]](#endnote-6) |
|  | IDE# | Click or tap here to enter text. |

3. Abbreviated IDE

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 3.1 |  | One of the following is true[[7]](#endnote-7): | | | | | | | |
|  | 3.1.1 | The FDA has NOT determined the device to be NSR | | | | | | | |
|  |  | 3.1.1.1 | The device is NOT banned8 | | | | | | |
|  |  | 3.1.1.2 | One of the following is true: | | | | | | |
|  |  |  | 3.1.1.2.1 | | | | | | The device is NOT intended as an implant |
|  |  |  | 3.1.1.2.2 | | | | | | 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 the subject |
|  |  | 3.1.1.3 | One of the following is true: | | | | | | |
|  |  |  | 3.1.1.3.1 | | | | | The device is NOT purported or represented to be for use in supporting or sustaining human life | |
|  |  |  | 3.1.1.3.2 | | | | | Even though the device is purported or represented to be for 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 | |
|  |  | 3.1.1.4 | One of the following is true: | | | | | | |
|  |  |  | 3.1.1.4.1 | | | | The device is NOT for use of substantial importance in diagnosing, curing, mitigating, or treating a disease, or otherwise preventing impairment of health | | |
|  |  |  | 3.1.1.4.2 | | | | Even though the device is for a use of substantial importance in diagnosing, curing, mitigating, or treating a disease, or otherwise preventing impairment of health, the device does NOT present a potential for serious risk to the health, safety, or welfare of a subject | | |
|  |  | 3.1.1.5 | The device does NOT otherwise present a potential for serious risk to the health, safety, or welfare of a subject | | | | | | |
|  |  | 3.1.1.6 | One of the following is true: | | | | | | |
|  |  |  | 3.1.1.6.1 | | | The device is NOT an *in vitro* companion diagnostic device | | | |
|  |  |  | 3.1.1.6.2 | | | The device is an *in vitro* companion diagnostic device | | | |
|  |  | 3.1.1.7 | The submission includes a brief explanation that the device is NSR | | | | | | |
|  |  | 3.1.1.8 | One of the following is true: | | | | | | |
|  |  |  | 3.1.1.8.1 | | The convened IRB agrees with the sponsor’s explanation that the device is NSR | | | | |
|  |  |  | 3.1.1.8.2 | | The convened IRB has documented in writing its own rational that the devices is NSR | | | | |
|  |  | 3.1.1.9 | One of the following is true: | | | | | | |
|  |  |  | 3.1.1.9.1 | The submission does NOT include the device packaging | | | | | |
|  |  |  | 3.1.1.9.2 | The device packaging includes the statement “CAUTION—Investigational device. Limited by Federal (or United States) law to investigational use.” | | | | | |
|  | 3.1.2 | The FDA has determined the device to be NSR | | | | | | | |

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 approval3 | |
|  |  | PMA # | Click or tap here to enter text. |
|  | 4.2.2 | The device has 510(k) clearance9 | |
|  |  | 501(k) # | Click or tap here to enter text. |
|  | 4.2.3 | The device has HDE approval5 | |
|  |  | HDE # | Click or tap here to enter text. |
|  | 4.2.4 | The device is a Class I/II exempt from pre-market notification requirements10[[8]](#endnote-8) | |
|  |  | Reg # | Click or tap here to enter text. |
| 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 procedure11 |

6. IDE Exempt: Custom Device

|  |  |  |
| --- | --- | --- |
| 6.1 |  | The device is a custom device12 |
| 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 Application13

|  |  |  |
| --- | --- | --- |
| 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 Device14

|  |  |  |
| --- | --- | --- |
| 9.1 |  | The clinical investigation evaluates a device that is a “low risk general wellness device” that falls under FDA enforcement discretion |

10. Combination Product15

|  |  |  |
| --- | --- | --- |
| 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 Evidence16

|  |  |  |
| --- | --- | --- |
| 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 States17

|  |  |  |
| --- | --- | --- |
| 12.1 |  | The research will be conducted outside of the United States |
| 12.2 |  | One of the following is true: |
|  | 12.2.1 | The sponsor does not intend to submit data to FDA |
|  | 12.2.2 | The study will be conducted in accordance with good clinical practice (GCP) |

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** [↑](#endnote-ref-1)
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)

   Recognized by the FDA as an approved device

   Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease; or

   Intended to affect the structure or any function of the boy 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. [↑](#endnote-ref-2)
3. 21 CFR §812.2 [↑](#endnote-ref-3)
4. [FDA Guidance: Frequently Asked Questions About Medical Devices](https://www.fda.gov/media/75381/download) [↑](#endnote-ref-4)
5. [FDA Guidance: Humanitarian Device Exemption (HDE) Program](https://www.fda.gov/media/74307/download) [↑](#endnote-ref-5)
6. Investigator brochures are not sufficient for documentation because they are not protocol-specific. Sponsors investigators require documentation from the FDA . [↑](#endnote-ref-6)
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 under 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 [↑](#endnote-ref-7)
8. See FDA [List of Banned Devices](https://www.fda.gov/medical-devices/medical-device-safety/medical-device-bans)

   9 21 CFR §812.2(c)(1)-(2)

   10 See FDA [List of Class I/II Exempt Devices](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm)

   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 need of the physician or dentist in the course of professional practice.

   13 [Guidance for Industry and Food and Drug Administration Staff: Policy for Device Software Functions and Mobile Medial Applications](https://www.fda.gov/media/80958/download)

   14 [Guidance for Industry and Food and Drug Administration Staff: General Wellness: Policy for Low Risk Devices](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices)

   15 [Guidance for Industry and Food and Drug Administration Staff: In Vitro Companion Diagnostic Devices](https://www.fda.gov/media/81309/download)

   16 [Guidance for Industry and Food and Drug Administration Staff: Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices](https://www.fda.gov/media/99447/download)

   17 [Guidance for Industry and Food and Drug Administration Staff: FDA Acceptance of Foreign Clinical Studies Not Conducted Under an IND](https://www.fda.gov/media/83209/download) [↑](#endnote-ref-8)