RUTGERS UNIVERSITY
Office for Research

| **WORKSHEET:** Devices | | |
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| 8.203 (HRP-307) | 04.24.2024 | 1 of 2 |

The purpose of this worksheet is to provide support for IRB staff, IRB Committee, or Designated Reviewer. This worksheet is to be used. It does not need to be completed or retained.

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| **1** | **Device Applicability** (Check if **"Yes"**. If either is **"Yes"** use the rest of the worksheet. Otherwise FDA device regulations do not apply.) | |
| ☐ | Does the activity involve the following? **(Check all that apply)**<br>☐ In the United States: The use of a device[i] in one or more persons that evaluates the safety or effectiveness of that device.<br>☐ Data regarding subjects or control subjects submitted to or held for inspection by FDA[ii].<br>☐ Data regarding the use of a device on human specimens (identified or unidentified) submitted to or held for inspection by FDA[iii]. | |
| ☐ | Does this involve a humanitarian use device? | |
| **2** | **IDE/HDE Requirements**[iv] (Check if **"Yes"**. One must be **"Yes"** If all are **"No"** IDE/HDE information is not complete.) | |
| ☐ | The device has an IDE or HDE. (Complete Sections 3 and 4) | |
| ☐ | The device qualifies for an abbreviated IDE. (Complete Section 4 and 5) | |
| ☐ | The device is exempt from the IDE requirements. (Complete Section 6) | |
| **3** | **IDE/HDE Validation** (Check if **"Yes"**. At least one must be **"Yes"** If all are **"No"**, IDE/HDE cannot be validated.) | |
| ☐ | Sponsor protocol imprinted with the IDE/HDE number. | |
| ☐ | Written communication from the sponsor documenting the IDE/HDE number. | |
| ☐ | Written communication from the FDA documenting the IDE/HDE number. *(Required if the investigator holds the IDE/HDE.)* | |
| **4** | **Device Control** (Check if **"Yes"**. Must be **"Yes"** If **"No"**, information regarding device control is incomplete.) | |
| ☐ | The plan for storage, control, and dispensing of the device is adequate to ensure that only authorized investigators will use the device and that they will use the device only in subjects who have provided consent.[v] | |
| **5** | **Abbreviated IDE** (Check if **"Yes"**. All must be **"Yes"**) | |
| ☐ | The device is not banned by the FDA. | |
| ☐ | The investigator will label the device in accordance with FDA regulations. (21 CFR §812.5) | |
| ☐ | The IRB will approve the research under 21 CFR §50 and §56 and determine that the study is not a significant risk[vi] | |
| ☐ | The investigator will comply with FDA requirements for monitoring investigations. (21 CFR §812.46) | |
| ☐ | The investigator will comply with FDA requirements for records and reports. (21 CFR §812.140, 21 CFR §812.150) | |
| ☐ | The investigator will not market or promote the device. (21 CFR §812.7) | |
| **6** | **IDE Exemptions** (Check if **"Yes"**. All criteria under one category must be **"Yes"** for a category to be met. If none of the categories is met, the device is not exempt from an IDE.) | |
| **Cat. #1** | ☐ | The device was not regulated as a drug before enactment of the Medical Device Amendments. (Transitional device.) |
| | ☐ | The device is FDA-approved/cleared.[vii] |
| | ☐ | The device is being used or investigated in accordance with the indications in the FDA approved/cleared labeling. |
| **Cat. #2** | ☐ | The device is a diagnostic device. |
| | ☐ | The sponsor will comply with applicable requirements in 21 CFR 809.10(c). |
| | ☐ | The testing is noninvasive.[viii] |
| | ☐ | The testing does not require an invasive sampling procedure that presents significant risk. |
| | ☐ | The testing does not by design or intention introduce energy into a subject |
| | ☐ | The testing is not used as a diagnostic procedure without confirmation by another, medically established product or procedure. |
| **Cat. #3** | ☐ | The device is undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, and the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk. |
| **Cat. #4** | ☐ | The device is a custom device as defined in 21 CFR 812.3(b) and is NOT being used to determine safety or effectiveness for commercial distribution. |

| 7 | **IDE Oversight for investigators who hold the IDE** (Check if **"Yes"**. One of the following must be **"Yes"** if the investigator holds the IDE) |
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| ☐ | The FDA regulatory requirements of a sponsor (including GMP when applicable) have been assumed by a contract research organization. |
| ☐ | An audit documents that the investigator is compliant with FDA sponsor requirements (including GMP when applicable). |

[i] The term ''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:
(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, 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.

[ii] This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement.

[iii] This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement.

[iv] If there are questions about which category is appropriate, have the investigator apply for an IDE following 21 CFR §812.20.

[v] The investigator or other designated individual must maintain records of the product's delivery to the clinical trial site, the inventory at the site, the use by each subject, and the return to the Sponsor or alternative disposition of unused products. These records include dates, quantities, batch or serial numbers, and expiration dates (if applicable), and the unique code numbers assigned to the investigational products and trial subjects.

[vi] The risk determination is based on the proposed use of a device in an investigation, and not on the device alone. (See http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm126418.pdf)

[vii] In commercial distribution immediately before May 28, 1976, or FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.

[viii] Blood sampling that involves venipuncture is considered non-invasive for purposes of this exemption. The use of surplus samples of body fluids or tissues that are left over from samples taken for non-investigational purposes is also considered non-invasive. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071230.pdf