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| --- | --- | --- |
|  | Diagram  Description automatically generated | **FORM: Device Supplement** |

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| --- | --- | --- | --- |
| **Date:** |  | | |
| **FHIRB #:** |  | | |
| **RG #:** |  | **Protocol #:** |  |
| **Principal Investigator:** |  | | |
| **Study Title:** |  | | |

**Instructions:**

Complete and attach this supplement to your submission in Hutch IRB to provide supporting information. Complete one supplement per device.

**Identify the device (includes software functions and in vitro diagnostic tests):**

|  |  |
| --- | --- |
| Name of Device → |  |
| Name of Manufacturer → |  |

Regulatory Status of Device. Please indicate the regulatory status of this device by checking one of the following:

1.  **The device is either exempt from IDE regulation under 21 CFR 812.2(c) or does not meet the definition of a medical device**. Check the appropriate checkboxes below to justify which listed context below fits the use of the device for your study:

Use of a device in commercial distribution and is used or investigated in accordance with the indications in labeling;

Use of a device in commercial distribution that FDA has determined to be substantially equivalent to a device in commercial distribution and that is used or investigated in accordance with the indications in the labeling;

Use of a diagnostic device, if the sponsor complies with applicable labeling requirements and if the testing:

1. Is noninvasive
2. Does not require an invasive sampling procedure that presents significant risk
3. Does not by design or intention introduce energy into a subject, and
4. Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

Use of a device undergoing consumer preference testing, testing of a modification, or testing of a combination of devices if the device(s) are legally marketed device(s) [that is, the devices have an approved PMA, cleared Premarket Notification 510(k), or are exempt from 510(k)] AND if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk;

A device intended solely for veterinary use;

A device shipped solely for research on or with laboratory animals and appropriately labeled; or

A custom device unless the device is being used to determine safety or effectiveness for commercial distribution.

Software function that does not meet the definition of a medical device (see [FDA Policy for Device Software Functions and Mobile Medical Applications](https://www.fda.gov/media/80958/download), Section III and Appendix A).

*IRO Staff: Only if this final box is checked, do* ***not*** *code the study as FDA-regulated.*

2.  **Humanitarian Use Device** with an HDE under 21 CFR 814. → Submit a copy of the HDE approved order from FDA, a device description, and any additional information about the device to help the IRB evaluate its use.

3.  **Nonsignificant Risk** (abbreviated IDE). Select one of the following to explain why this is not considered a significant risk device.

Submit letter from sponsor explaining rationale.

Software function that may meet the definition of a device but for which FDA intends to exercise enforcement discretion (see [FDA Policy for Device Software Functions and Mobile Medical Applications](https://www.fda.gov/media/80958/download), Section V.B and Appendix B).

*IRO Staff: This study would still be coded as FDA-regulated.*

4.  **Significant Risk Device Requiring an IDE** application with the FDA

4.1 Date the IDE application was submitted to FDA:

4.2 The status of the IDE:

Pending FDA approval

Approved → *if approved,* complete the table below and check the appropriate checkbox:

|  |  |
| --- | --- |
| Holder of IDE |  |
| Location of IDE Holder (i.e., Fred Hutch, other university, non-profit, or drug company) |  |
| Class of IDE (select one) | I  II  III |

Written communication from the FDA documenting the IDE number → Attach a copy of documentation in Hutch IRB

Written communication from the sponsor (not the PI) → Attach copy

Sponsor protocol with the IDE number → Attach copy

Other, explain:

|  |
| --- |
|  |

4.3 Please describe your plan to control the use, and distribution, of the investigational device.

|  |
| --- |
|  |

4.4 Has this plan been evaluated by CRS Regulatory Affairs?

Yes → Submit correspondence showing agreement to the device control plan to this application.

No → Contact Regulatory Affairs at [RegulatoryAffairs@fredhutch.org](mailto:RegulatoryAffairs@fredhutch.org) to review and approve the plan.