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| |  | | --- | | Device Worksheet  **Version Date – FOR OHR USE: 11/1/18**  Determining whether FDA regulations governing device research apply | | |
| **Principal Investigator:** | Name of device: |
| **Title of Study:** | |
| Section 1: Investigational Status | |
| Please select the appropriate status.  This device is FDA-approved. Proceed to Section 2  The device has an IDE/HDE number. Proceed to Section 3  The device is exempt from the requirement to have an IDE. Proceed to Section 4  This is a non-significant risk device. Proceed to Section 5 | |
| Section 2: The device is FDA-approved. | |
| The device is FDA approved  Device is used in accordance with its approved indication  FDA regulations involving device research apply when either of the following is true:   |  | | --- | | The activity will evaluate the safety or effectiveness of a device in one or more persons (21 CFR 812.2(a))  Data regarding the use of a device on human specimens will be submitted to or held for inspection by FDA as part of an application for a research or marketing permit. |   When FDA regulations apply, the IRB needs to verify the device has an IDE, or is exempt from requirements to have an IDE. | |
| Section 3: The device has an IDE/HDE number. | |
| The device has an IDE/HDE, which has been verified by at least one item listed below:   |  | | --- | | the IDE/HDE number is listed or stamped on the commercial sponsor protocol  communication from the commercial sponsor  communication from the FDA | | |
| Section 4: The device is exempt from the requirement to have an IDE (21 CFR 812.2(c)). | |
| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Select the option that applies:   |  | | --- | | Option 1: Devices in commercial distribution immediately before May 28, 1976. All items below must be true.  Is not a transitional device (A device subject to section 520(l) of the FD&C Act and which FDA previously regulated as a new drug or an antibiotic drug before May 28, 1976)  Has been in commercial distribution immediately before May 28, 1976  Is being used or investigated in accordance with the indications in labeling in effect at that time |  |  | | --- | | Option 2: Devices in commercial distribution on or after May 28, 1976. All items below must be true.  Is not a transitional device  Was introduced into commercial distribution on or after May 28, 1976  The FDA has determined it to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976  Is being used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence |  |  | | --- | | Option 3: Diagnostic device. All items listed below must be true.  Is a diagnostic device  The sponsor will comply with applicable requirements in 21 CFR §809.10(c)  The testing:  Is noninvasive  Does not require an invasive sampling procedure that presents significant risk  Does not by design or intention introduce energy into a subject  Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure |  |  | | --- | | Option 4: Consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution. All items listed below must be true.  Is undergoing consumer preference testing  Involves testing of a modification, or testing of a combination of two or more devices in commercial distribution  The testing is not for the purpose of safety or efficacy  The testing does not put participants at risk |  |  | | --- | | Option 5: Custom devices. All items listed below must be true.  The device is a custom device as defined in 21 CFR §812.3(b)  The custom device is not being used to determine safety or effectiveness for commercial distribution | | | |

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| Section 5: The device is non-significant risk and meets the requirements for an abbreviated IDE. | | |
| |  | | --- | | All items listed below must be true.  The device is not a banned device  The sponsor labels the device in accordance with 21 CFR 812.5  The sponsor has provided a brief explanation of why the device is not a significant risk device or FDA has issued concurrence documenting this  The sponsor ensures that each investigator participating in an investigation of the device obtains from each subject under the investigator’s care, consent under 21 CFR 50 and documents it, unless documentation is waived  The sponsor complies with the requirements of 21 CFR 812.46 with respect to monitoring investigations  The sponsor maintains the records required under 21 CFR 812.140(b) (4) and (5) and makes the reports required under 21 CFR 812.150(b) (1) through (3) and (5) through (10)  The sponsor ensures that participating investigators maintain the records required by 21 CFR 812.140(a)(3)(i) and make the reports required under 812.150(a) (1), (2), (5), and (7)  The sponsor complies with the prohibitions in 21 CFR 812.7 against promotion and other practices  **If the IRB does not accept the rationale for the device being non-significant risk, the sponsor must obtain from the FDA either an IDE or a concurrence that the device is non-significant risk.** | | | |
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| PI Signature |  | Date |