UC San Diego
INSTITUTIONAL REVIEW BOARD ADMINISTRATION

OIA-418 CHECKLIST: Non-Significant Risk Device

NUMBER	DATE	PAGE
OIA-418	09/06/2023	1 of 1

The purpose of this checklist is to provide support for IRB members or the designated reviewer following the *OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations*, or equivalent, when research involves an abbreviated Investigational Device Exemption (IDE) or IDE exempt device. This checklist, or equivalent, may be used for all reviews (initial, continuing, amendment, review by the convened IRB, and review using the expedited procedure). It does not need to be completed or retained.

IRB Number:	
Investigator:	

1 IDE EXEMPT DEVICE STUDY[1] (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.)

Category #1	☐	The device was not regulated as a drug before enactment of the Medical Device Amendments. (Transitional device)
	☐	The device is Food and Drug Administration (FDA)-approved/cleared.[2]
	☐	The device is being used or investigated in accordance with the indications in the FDA approved/cleared labeling.
Category #2	☐	The device is a diagnostic device.
	☐	The sponsor will comply with applicable requirements in 21 CFR 809.10(c).
	☐	The testing is noninvasive.[3]
	☐	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.
Category #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.
Category #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.

2 SIGNIFICANT RISK DEVICE[4] **STUDY** (Check if **"Yes."** If any box is checked, the device is significant risk and must be submitted to FDA.)

☐	Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject.
☐	Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject.
☐	Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject.
☐	Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

3 NON-SIGNIFICANT RISK DEVICE STUDY – ABBREVIATED IDE (Check if **"Yes."**)

☐	Meets none of the above criteria in box 2.

Rationale (Describe using protocol specific findings):

[1] 21 CFR 812.2
[2] 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
[3] 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. FDA Guidance - In Vitro Diagnostic (IVD) Devices Studies - Frequently Asked Questions
[4] 21 CFR 812.3(m)