UNIVERSITY OF MIAMI

CHECKLIST: Devices		
NUMBER	DATE	PAGE
HRP-418	06.04.2019	1 of 2

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following the WORKSHEET: Criteria for Approval and Additional Considerations (HRP-314) when research involves an abbreviated IDE or IDE exempt device. This checklist or equivalent must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist or equivalent to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist or equivalent to CHECKLIST: Non-Committee Review (HRP-402) or equivalent. The IRB Administration retains this checklist or equivalent in the protocol file.
- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist or equivalent made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the TEMPLATE MINUTES (HRP-501) to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist or equivalent does not need to be completed or retained.
  2. The convened IRB completes this checklist or equivalent to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Administration retains this checklist or equivalent in the protocol file.

IRB Number:	
Investigator:	

1 **SIGNIFICANT RISK DEVICE STUDY** (Check if **"Yes".** If any box is checked, the device is significant risk and must be submitted to the 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.

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

☐	Meets none of the above criteria in box 1.

Rationale (Describe using protocol specific findings):

3 **IDE EXEMPT DEVICE STUDY** (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 FDA-approved/cleared.[i]
	☐	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.[ii]
	☐	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.

[i] 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.

[ii] 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