

	CHECKLIST: Non-Significant Risk Device			IRB #: \$\$IRB Number\$\$
	NUMBER	DATE	PAGE	Review Type: \$\$Review\$\$
	HRP-424	10/21/2021	1 of 1	Status: \$\$Status\$\$

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following “HRP 311 Worksheet: Criteria for Approval and Additional Considerations” when reviewing research involving *devices*. This checklist must be used for the initial review and applicable modifications by the convened IRB.

- For initial review using the convened IRB and for modifications where the determinations relevant to this checklist made on the previous review have changed, complete the following:

The IRB Analyst for the convened IRB meeting completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.

1 SIGNIFICANT RISK DEVICE: (One or more are “Yes”)

<input type="checkbox"/> Yes <input type="checkbox"/> No	Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject.
<input type="checkbox"/> Yes <input type="checkbox"/> No	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.
<input type="checkbox"/> Yes <input type="checkbox"/> No	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.
<input type="checkbox"/> Yes <input type="checkbox"/> No	Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

2 NON-SIGNIFICANT RISK DEVICE

<input type="checkbox"/> Yes <input type="checkbox"/> No	Meets none of the above criteria.
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3 RATIONALE (Describe)