



**WORKSHEET: Non-Significant Risk Device**

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8.201 (HRP-418)	5/1/2024	1 of 1

The purpose of this worksheet is to provide support for IRB members or the Designated Reviewer following 4.202 (HRP-314) WORKSHEET: Criteria for Approval when research involves an abbreviated IDE. This worksheet may 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 worksheet made on the previous review have changed, the Designated Reviewer may utilize this worksheet to make determinations required by the regulations along with protocol-specific findings justifying those determinations. The Designated Reviewer attaches this checklist to “Submit Designated Review” activity in eIRB+.
- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this worksheet made on the previous review have changed, the convened IRB 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 STUDY (Check if “Yes”. If any are checked, the device is a significant risk device.)**

- 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 (Check if “Yes”).**

- Meets none of the above criteria.

**3 RATIONALE (Describe)**