



HRP-418 | 1/1/2024

CHECKLIST: Non-Significant Risk Device

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

- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist 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 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.
 2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist in the "Submit Committee Review" activity and retains this checklist in the protocol file.

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)

IRB Considerationsⁱⁱ:

- *The risk determination is based on the proposed use of a device in an investigation, and not on the device alone.*
- *Consider the potential harm any additional procedures the subject will need to undergo as part of the investigational study (e.g., surgical procedure)*

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ⁱ This document satisfies AAHRPP elements II.5.A, II.5.B

ⁱⁱ Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors, Significant Risk and Nonsignificant Risk Medical Device Studies, January 2006, <https://www.fda.gov/media/75459/download>