HRP-418 | 3/29/2024

CHECKLIST: Non-Significant Risk Device

The purpose of this checklist is to provide support for IRB members 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). [[1]](#endnote-2)

* For initial review using the convened IRB and for modifications and continuing reviews, 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.
* Note the determination is based on the use of the device and the investigation (study), not the use of the device alone. Documentation from the FDA has to be related to the specific study in question.

Submission Information

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| **Basic Information** | **Submission Details** |
| IRB Number: | Click or tap here to enter text. |
| Study Title: | Click or tap here to enter text. |
| Short Title: | Click or tap here to enter text. |
| Investigator: | Click or tap here to enter text. |
| Person/Panel Completing Checklist (Name): | Click or tap here to enter text. |
| Date Checklist Completed: | Click or tap here to enter text. |

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.

1. NON-SIGNIFICANT RISK DEVICE STUDY (Check if “Yes.”)

Meets none of the above criteria.

1. RATIONALE (Describe)

*IRB Considerations[[2]](#endnote-3):*

* *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)*

Click or tap here to enter text.

1. This document satisfies AAHRPP elements II.5.A, II.5.B [↑](#endnote-ref-2)
2. 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> [↑](#endnote-ref-3)