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| --- | --- | --- | --- | --- | --- |
| Study ID#: |  | PI: |  | Funding Source: |  |

**This form must be completed by the convened IRB for all clinical investigations that involve significant risk or non-significant risk medical devices that are not IDE exempt.**

* The Investigational Device Exemptions (IDE) regulation (21 CFR 812) describes three types of device studies: significant risk (SR), nonsignificant risk (NSR), and exempt studies.
* Sponsors are responsible for making the initial risk determination and presenting it to the IRB.
* Unless FDA has already made a risk determination for the study, the IRB must review the sponsor's SR or NSR determination for every investigational medical device study reviewed and modify the determination if the IRB disagrees with the sponsor.
* If FDA has already made the SR or NSR determination for the study, the agency's determination is final.

**Information Received**

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| --- |
| Confirm that the IRB has received the following information by checking the relevant boxes below: |
| Initial device risk determination made by the sponsor |
| Explanation provided by the sponsor to the IRB of why the device is not a significant risk device  Sponsor’s risk assessment (for both NSR or SR)  Sponsor’s rationale used in making its SR or NSR determination |
| Any additional information provided by the sponsor that will assist the IRB in the determination |
| FDA determination, if any |
| Description of the device |
| Reports of prior investigations conducted with the device |
| The proposed investigational plan |
| Subject selection criteria |
| Copy of FDA approval of IDE application for significant risk devices, if appropriate |
| Any other supporting documents, please list: |

**FDA Determination**

No  Yes Has the FDA made a determination of the risk level of the device?

If yes, the FDA’s determination was:

NSR

SR

*If yes: If the FDA has provided the device risk determination, the IRB still needs to make and document the determination; however, if the device risk determination has been made by the FDA, the determination of the FDA is final.*

**IRB Device Risk Determination**

The IRB should consider the following in making the determination:

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| * Proposed use of the device, not the device alone * Nature of harm that may result from use of the device |
| * Any additional procedures required as part of the clinical investigation and potential harm from the procedure and the device |

Is the device:

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| --- |
| Yes  No Intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; or |
| Yes  No 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; or |
| Yes  No 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; or |
| Yes  No Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject. 21 CFR 812.3(m) |

*To be a non-significant risk device, none of the boxes above can be checked yes. An NSR device study is one that does not meet the definition for an SR device study.*

**The IRB has determined that the device is:**

Significant risk

* If the IRB disagrees with the Sponsor’s NSR assessment and decides the study is SR, the IRB must notify the clinical investigator and where appropriate, the sponsor (21 CFR 812.66); *notify clinical investigator and sponsor*
* An IDE application is required and the sponsor may not begin the investigation until 21 CFR 812.30(a) is met (21 CFR 812.66)

Non-significant risk (does not meet the definition of a significant risk device)

* The study must meet the requirements for an Abbreviated IDE under 21 CFR 812.2(b)(1); *complete the HRP-420 – Checklist – Abbreviated IDE Documentation for IRB*

More information needed,

Reason for the determination:

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Comments:

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| Full Board IRB determination made by: | | | |
|  | | | |
| Name of individual completing this form: |  | Meeting date |  |
|  | | | |

NOTE: the IRB must also review and approve the study in accordance with 21 CFR 50 and 21 CFR 56 before the study may begin.