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| The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following the WORKSHEET: Criteria for Approval (HRP-314) when research involves an abbreviated IDE. This checklist must be used for all initial reviews and for any other review where the determination changes.[[1]](#footnote-1)   * For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer upload this checklist in the Submit Designated Review activity in ETHOS. * 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, the convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The IRB Analyst uploads this checklist in the Submit Committee Review activity in ETHOS. * 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. | | |
| **IRB Number:** | |  |
| **Protocol Name:** | |  |
| **Investigator:** | |  |
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| 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. | |
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| 1. NON-SIGNIFICANT RISK DEVICE STUDY (Check if “Yes”.) | | |
|  | Meets none of the above criteria. | |
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| 1. RATIONALE (Describe) | | |
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1. This document satisfies AAHRPP elements II.5.A, II.5.B [↑](#footnote-ref-1)