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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 reviews (initial, continuing, modification, review by the Full [convened] IRB, and review using the single member [expedited] procedure.)   * For initial review using the single member (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 attaches this checklist to CHECKLIST: HRPP and Single Member Review (HRP-402). The HRPP Office retains this checklist in the protocol file. * For initial review using the Full (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 Full (convened) IRB completes the corresponding section of the TEMPLATE MINUTES (HRP-501) 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 Full (convened) IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the HRPP Office retains this checklist in the protocol file. | |
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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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