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| 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, and review using the expedited procedure). [[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 attaches this checklist to “Submit Non-Committee Review” activity. The HSRO retains this checklist in the protocol file. * 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 HSRO staff uploads this checklist in the “Submit Committee Review” activity and retains this checklist in the protocol file. | | | | | |
| **IRB Number:** | | | |  | |
| **Study Title:** | | | |  | |
| **Short Title:** | | | |  | |
| **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 in box 1. | | | |
|  | | The device is not banned by the FDA. | | | |
|  | | The investigator will label the device in accordance with FDA regulations. (21 CFR §812.5) | | | |
|  | | The IRB will approve the research under 21 CFR §50 and §56 and determine that the study is not a significant risk[[2]](#endnote-1) | | | |
|  | | The investigator will comply with FDA requirements for monitoring investigations. (21 CFR §812.46) | | | |
|  | | The investigator will comply with FDA requirements for records and reports. (21 CFR §812.140, 21 CFR §812.150) | | | |
|  | | The investigator will not market or promote the device. (21 CFR §812.7) | | | |
| Rationale (Describe using protocol specific findings): | | | | |
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| 1. IDE Exemptions (Check if “Yes”. All criteria under one category must be “Yes” for a category to be met. If none of the categories is met, the device is not exempt from an IDE.) | | | | | |
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| **Cat. #1** | |  | The device was not regulated as a drug before enactment of the Medical Device Amendments. (Transitional device.) | | |
|  | The device is FDA-approved/cleared.[[3]](#endnote-2) | | |
|  | The device is being used or investigated in accordance with the indications in the FDA approved/cleared labeling. | | |
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| **Cat. #2** | |  | The device is a diagnostic device. | | |
|  | The sponsor will comply with applicable requirements in 21 CFR 809.10(c). | | |
|  | The testing is noninvasive.[[4]](#endnote-3) | | |
|  | The testing does not require an invasive sampling procedure that presents significant risk. | | |
|  | The testing does not by design or intention introduce energy into a subject | | |
|  | The testing is not used as a diagnostic procedure without confirmation by another, medically established product or procedure. | | |
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| **Cat. #3** | |  | The device is undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, and the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk. | | |
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| **Cat. #4** | |  | The device is a custom device as defined in 21 CFR 812.3(b) and is NOT being used to determine safety or effectiveness for commercial distribution. | | |
| 1. Devices in which the FDA intends to exercise enforcement discretion[[5]](#endnote-4) (Check if “Yes”. If any are “Yes,” the device is not subject to the device regulatory requirements at this time[[6]](#endnote-5). ) | | | | | |
|  | | A software function that helps patients (i.e. users) self-manage their diseases or conditions without providing specific treatment or treatment suggestions. | | | |
|  | | A software function that automates simple tasks for health care providers. | | | |

1. This document satisfies AAHRPP elements II.5.A, II.5.B [↑](#footnote-ref-1)
2. The risk determination is based on the proposed use of a device in an investigation, and not on the device alone. (See <http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm126418.pdf>) [↑](#endnote-ref-1)
3. In commercial distribution immediately before May 28, 1976, or FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence. [↑](#endnote-ref-2)
4. Blood sampling that involves venipuncture is considered non-invasive for purposes of this exemption. The use of surplus samples of body fluids or tissues that are left over from samples taken for non-investigational purposes is also considered non-invasive. <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071230.pdf> [↑](#endnote-ref-3)
5. Examples of software functions where the FDA is exercising enforcement discretion can be found in the [Policy for Device Software Functions and Mobile Medical Apps](https://www.fda.gov/media/80958/download). [↑](#endnote-ref-4)
6. For software and mobile apps in this category, the FDA strongly recommends that manufacturers that may meet the definition of a device follow the Quality System regulation (that includes good manufacturing practices) in the design and development of their device software functions, and initiate prompt corrections to their devise, when appropriate, to prevent patient and user harm. [↑](#endnote-ref-5)