Saint Louis University Institutional Review Board

Additional Criteria for Investigational Devices

*Check if “Yes” or “N/A.”*

*This worksheet is intended to provide support for individuals in determining how research activity should be regulated. This worksheet is not meant to be retained.*

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| **1 - Device Applicability** | | |
|  | The research activity involves the following:(Check all that apply)  *Note: If “Yes” for any, then complete the remainder of the form. If “No,” FDA regulations do not apply.*  The use of a device in one or more persons that evaluates the safety or effectiveness of that device.[[1]](#endnote-1)  Data regarding subjects or controls submitted to or held for review by the FDA. [[2]](#endnote-2)  Data regarding the use of a device on human specimens (identified or unidentified) submitted to or held for inspection by the FDA.[[3]](#endnote-3) | |
|  | The research involves a humanitarian use device (HUD). | |
| **2 – IDE/HDE Requirements[[4]](#endnote-4)** (MUST check at least one) | | |
|  | The device has a valid IDE or HDE. (Complete Sections 3 and 4) | |
|  | The device qualifies for an abbreviated IDE. (Complete Section 5) | |
|  | The device is exempt from IDE requirements. (Complete Section 6) | |
| **3 – IDE/HDE Validation** (MUST check at least one) | | |
|  | Protocol includes written communication from the sponsor documenting the IDE/HDE number. | |
|  | Sponsor protocol is imprinted with the IDE/HDE number. | |
|  | Protocol includes written communication from the FDA documenting the IDE/HDE number.  *Note: This is required if the investigator holds the IDE/HDE. Also complete section #7.* | |
| **4 – Device Control** | | |
|  | Protocol outlines the plan for storage, control and dispensing of the device and the plan is adequate to ensure only authorized personnel will use the device in study participants. Dispensing logs should be kept. | |
| **5 – Abbreviated IDE** (MUST check ALL) | | |
|  | Protocol includes an explanation of why the device is not a significant risk device. | |
|  | The IRB will approve the research, determine that the device is a non-significant risk device, and ensure that consent will be obtained and documented in accordance with FDA regulation.[[5]](#endnote-5) | |
|  | Investigators are meeting [additional FDA requirements](https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/additional_criteria_checklist_sponsor_investigator_responsibilities.docx) for abbreviated IDEs. | |
| **6 – IDE Exceptions**  *Note: All criteria for one category must be checked for the category to be met. If no categories are met, then the device is not exempt from an IDE.* | | |
|  | **Category #1: Approved Device** | |
|  | The device was not regulated as a drug before enactment of the Medical Device Amendments. (Transitional Device) |
|  | The device is FDA- approved/cleared.[[6]](#endnote-6) |
|  | The device is being used or investigated in accordance with the indication in the FDA approved/cleared labeling. |
| **Category #2: Diagnostic Device** | |
|  | The device is a diagnostic device. |
|  | The sponsor will comply with applicable requirements in 21 CFR 809.10(c). |
|  | The testing meets the following criteria:  Noninvasive[[7]](#endnote-7)  Does not require an invasive sampling procedure that presents significant risk  Does not by design or intention introduce energy in the subject  Not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established product or procedure. |
| **Category #3: Device Testing** | |
|  | 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. |
| **Category #4: Custom Device** | |
|  | 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. |
| **7 – Oversight for Investigators who hold the IDE** | | |
|  | Investigators are meeting [additional FDA requirements](https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/additional_criteria_checklist_sponsor_investigator_responsibilities.docx) when taking on the role of sponsor investigator (holding an IDE). | |

1. The term “device” means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

   Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to any of them,

   Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals, or

   Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. [↑](#endnote-ref-1)
2. This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to the FDA meet this requirement. [↑](#endnote-ref-2)
3. This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to the FDA meet this requirement. [↑](#endnote-ref-3)
4. If there are questions about which category is appropriate, have the investigator apply for an IDE following 21 CFR 812.20. [↑](#endnote-ref-4)
5. The risk determination is based on the proposed use of the device in an investigation, and not on the device alone. (See <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf>) [↑](#endnote-ref-5)
6. 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-6)
7. Blood sampling that involved 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. (See <http://www.fda.gov/downloads/MedicalDevices/.../ucm071230.pdf>) [↑](#endnote-ref-7)