|  |  |  |  |
| --- | --- | --- | --- |
| The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following “HRP 311 Worksheet: Criteria for Approval and Additional Considerations” when reviewing research involving *devices*.   * For initial review, modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the IRB Analyst completes this checklist. * For expedited reviews: the Designated Reviewer reviews the completed checklist and it is retained in the protocol file. * For review using the convened IRB: the IRB Analyst for the convened IRB meeting completes the corresponding section of the meeting minutes to document determinations required by the regulations, in which case this checklist does not need to be retained. | | | |
|  | | | |
| 1. Device Applicability (If either is “Yes” use the remainder of the worksheet. If both are “No” FDA device regulations do not apply.) | | | |
| Yes  No | | Does the activity involve the following? **(Check all that apply)**  In the United States: The use of a device[[1]](#endnote-1) in one or more persons that evaluates the safety or effectiveness of that device.  Data regarding subjects or control subjects submitted to or held for inspection by FDA[[2]](#endnote-2).  Data regarding the use of a device on human specimens (identified or unidentified) submitted to or held for inspection by FDA[[3]](#endnote-3). | |
| Yes  No | | Does this involve a humanitarian use device? | |
|  | | | |
| 1. IDE/HDE Requirements (One must be “Yes” If all are “No” IDE/HDE information is not complete.) | | | |
| Yes  No | | The device has an IDE or HDE. (Complete Sections 3 and 4) | |
| Yes  No | | The device qualifies for an abbreviated IDE. (Complete Section 4 and 5) | |
| Yes  No | | The device is exempt from the IDE requirements. (Complete Section 6) | |
|  | | | |
| 1. IDE/HDE Validation (At least one must be “Yes” If all are “No”, IDE/HDE cannot be validated.) | | | |
| Yes  No | | Sponsor protocol imprinted with the IDE/HDE number. | |
| Yes  No | | Written communication from the sponsor documenting the IDE/HDE number. | |
| Yes  No | | Written communication from the FDA documenting the IDE/HDE number. *(Required if the investigator holds the IDE/HDE.)* | |
|  | | | |
| 1. Device Control (Must be “Yes” If “No”, information regarding device control is incomplete.) | | | |
| Yes  No | | The plan for storage, control, and dispensing of the device is adequate to ensure that only authorized investigators will use the device and that they will use the device only in subjects who have provided consent.[[4]](#endnote-4) | |
|  | | | |
| 1. Abbreviated IDE requirements for NSR device (All must be “Yes”) | | | |
| Yes  No | | The device is not a banned by the FDA. | |
| Yes  No | | The investigator will label the device in accordance with FDA regulations. (21 CFR §812.5) | |
| Yes  No | | The IRB will approve the research under 21 CFR §50 and §56 and determine that the study is not a significant risk[[5]](#endnote-5). | |
| Yes  No | | The investigator will comply with FDA requirements for monitoring investigations. (21 CFR §812.46) | |
| Yes  No | | The investigator will comply with FDA requirements for records and reports. (21 CFR §812.140, 21 CFR §812.150) | |
| Yes  No | | The investigator will not market or promote the device. (21 CFR §812.7) | |
|  | | | |
| 1. IDE Exemptions (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.) | | | |
|  | | | |
| **Cat. #1** | Yes  No | | The device was not regulated as a drug before enactment of the Medical Device Amendments. (Transitional device.) |
| Yes  No | | The device is FDA-approved/cleared.[[6]](#endnote-6) |
| Yes  No | | The device Is being used or investigated in accordance with the indications in the FDA approved/cleared labeling. |
|  | | | |
| **Cat. #2** | Yes  No | | The device is a diagnostic device. |
| Yes  No | | The sponsor will comply with applicable requirements in 21 CFR 809.10(c). |
| Yes  No | | The testing is noninvasive.[[7]](#endnote-7) |
| Yes  No | | The testing does not require an invasive sampling procedure that presents significant risk.[[8]](#endnote-8) |
| Yes  No | | The testing does not by design or intention introduce energy into a subject |
| Yes  No | | The testing is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.[[9]](#endnote-9) |
|  | | | |
| **Cat. #3** | Yes  No | | 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. |
|  | | | |
| **Cat. #4** | Yes  No | | 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. 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 Pharmacopeia, or any supplement to 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 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 FDA meet this requirement. [↑](#endnote-ref-3)
4. The investigator or other designated individual must maintain records of the product's delivery to the clinical trial site, the inventory at the site, the use by each subject, and the return to the Sponsor or alternative disposition of unused products. These records include dates, quantities, batch or serial numbers, and Expiration Dates (if applicable), and the unique code numbers assigned to the investigational products and trial subjects. [↑](#endnote-ref-4)
5. 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-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 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. [↑](#endnote-ref-7)
8. For example, the FDA considers sampling techniques that require biopsy of a major organ, use of general anesthesia, or placement of a blood access line to an artery or large vein (subclavian, femoral, or iliac) to be significant risk. <https://www.fda.gov/media/71075/download> [↑](#endnote-ref-8)
9. For an investigational study to be exempt under 21 CFR 812.2(c)(3), clinical investigators must use a medically established means of diagnosis (e.g., another cleared or approved IVD or culture) of the disease or condition as the basis for decisions regarding treatment of all subjects participating in the study. 21 CFR 812.2(c)(3)(iv). Additionally, test results from the exempt IVD investigation should not influence patient treatment or clinical management decisions before the diagnosis is established by a medically established product or procedure.

   If an investigational test uses a new technology or represents a significant technological advance, established diagnostic products or procedures may not be adequate to confirm the diagnosis provided by the investigational IVD. For example, if an investigational test is designed to identify an infection at the earliest stages of viral infection (before formation of antibodies), established diagnostic products or procedures that rely on the detection of antibodies to the virus would be inadequate to confirm diagnoses. Under these conditions the study would not meet the criteria for exemption under 812.2(c)(3) since the testing could not be confirmed with a medically established diagnostic product or procedure. You may consider whether the device is a non-significant risk device subject to abbreviated IDE requirements (21 CFR 812.2(b)). <https://www.fda.gov/media/71075/download> [↑](#endnote-ref-9)