Investigator Checklist for IDE Exempt, Non-Significant Risk or Significant Risk Devices

**Instructions**

The purpose of this checklist is to help investigators and the IRB determine whether an investigational device is IDE Exempt, Non-Significant Risk, or presents Significant Risk.

These determinations are needed only for devices that meet the FDA definition of [medical device](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm), which is “*an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:*

* *Recognized in the official National Formulary, or the Unites States Pharmacopoeia, 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 any of 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 any of its primary intended purposes*."

**Device Name & Manufacturer:**

**Investigator(s):**

1. **IDE Exempt Device Study**

*All criteria under at least one category must be Yes for the device to be exempt from the IDE requirement. If none of the categories for exemption apply (or if unsure), complete Section B.*

|  |  |  |
| --- | --- | --- |
| Category 1 |  | **Older Devices** (*this category is rarely used*): A device in commercial distribution (legally marketed in the U.S.) immediately before May 28, 1976, when used or investigated in accordance with the indications in the labeling that were in effect at that time. |
| Category 2 |  | **Substantial Equivalence (510(k) clearance)**: A device introduced into commercial distribution (legally marketed in the U.S.) on or after May 28, 1976, that the FDA has determined to be substantially equivalent (see [510(k) clearance database](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm)) to a device in commercial distribution and that is used or investigated in accordance with the indications in the labeling FDA reviewed in determining substantial equivalence |
| Category 3 | The device is a **diagnostic device** (e.g., in vitro diagnostics (IVDs), testing assays, laboratory developed tests (LDTs), and genomic sequencing): | |
|  | The testing is [**noninvasive**](https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071230.pdf). |
|  | The testing does not require an [**invasive**](https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071230.pdf) **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. |
|  | The sponsor will comply with applicable (**labeling**) requirements in 21 CFR 809.10. |
| Category 4 |  | The device is undergoing **consumer preference** testing, testing of a **modification**, or testing of a combination of two or more devices in commercial distribution (legally marketed in the U.S.), and the testing is **not for the purpose of determining safety or effectiveness** and does not put subjects at **risk**. |
| *Categories 5 & 6 are not applicable to human subject research. They are intentionally omitted.* | | |
| Category 7 |  | The device is a **custom device**, unless the device is being used to determine safety or effectiveness for commercial distribution. |

*If the response for one or more of the categories above is YES, the study is considered to be exempt from the IDE requirement. The study may then qualify for Expedited IRB Review Category 1 if the use of the device as proposed in the study under review is no greater than minimal risk. However, if the use of the device as proposed in the study under review is greater than minimal risk, the study may be reviewed in a Convened IRB Meeting by the IRB Board.*

**Please remember that the determination of risk is based on the use of the device as proposed in the study under review, *not on the device alone*.**

|  |  |  |
| --- | --- | --- |
| This device as proposed in the study under review… |  | Is No Greater than Minimal Risk |
|  | Is Greater than Minimal Risk |

1. **Non-Significant or Significant Risk**

*Indicate if the proposed use of the device in the study under review meets each criterion and provide a rationale for your response.*

**Please remember that the determination of risk is based on the use of the device as proposed in the study under review, *not on the device alone*.**

|  |  |  |
| --- | --- | --- |
| **Criterion** | **Yes/No** | **Rationale** |
| Device is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject?  **Reference: 21 CFR 812.3(m)(1)** |  |  |
| Device is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject?  **Reference: 21 CFR 812.3(m)(2)** |  |  |
| Device 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?  **Reference: 21 CFR 812.3(m)(3)** |  |  |
| Device otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.  **Reference: 21 CFR 812.3(m)(4)** |  |  |

*If the response for one or more of the criteria above is YES, the study is considered a Significant Risk Device. If none of the Significant Risk Device Study criteria are met, the IRB can make the NSR determination. If the IRB finds the study is NSR, the device is considered to have an Abbreviated IDE (21 CFR 812.2(b)).*

|  |  |  |
| --- | --- | --- |
| This device as proposed in the study under review… |  | Is Significant Risk |
|  | Is Non-Significant Risk |

1. **Investigator Attestation**

I attest that the information in this checklist is complete and accurate.

**Principal Investigator Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**