INVESTIGATIONAL DEVICE EXEMPT, HUD, SR OR NSR DETERMINATION CHECKLIST

Children's Hospital of Philadelphia
RESEARCH INSTITUTE

The purpose of this checklist is to assist CHOP Investigators in determining whether their device study falls under the Exempt HUD, Significant Risk (SR), or Non-Significant Risk (NSR) categories.

PI: _____

Study Title: _____

Date: _____

1. IDE Exempt Device Study: 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.

Category #1

- ☐ The device was not regulated as a drug before enactment of the Medical Device Amendments (Transitional Device)
- ☐ The device is FDA-approved/cleared.
- ☐ The device is being used or investigated in accordance with the indications in the FDA approved/cleared labeling.

Category #2

- ☐ The device is a diagnostic device.
- ☐ The sponsor will comply with applicable requirements in 21 CFR 809.10(c).
- ☐ The testing is non-invasive.
- ☐ 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.

Category #3

- ☐ The device is undergoing consumer preference testing, testing of 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

- ☐ 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.

2. Humanitarian Use Device (HUD): Check, if "Yes".

☐ Humanitarian Use Device used according to its FDA labeling requires only IRB review. If not used according to labeling as part of a clinical investigation, proceed to "**3. Significant Risk (SR Device Study**", to see if an FDA IDE is required. If an IDE does not appear to be required, then, proceed to "**4. Non-Significant Risk Device Study (NSR) - An "Abbreviated" IDE**", and complete the information in Section 4.

3. Significant Risk (SR Device Study: Check, if "Yes". If any box is checked, the device is significant risk and must be submitted to the FDA under IDE guidelines.

☐ 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 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 potential for serious risk to the health, safety, or welfare of a subject.

☐ Otherwise presents potential for serious risk to the health, safety, or welfare of a subject.

4. Non-Significant Risk Device Study (NSR) - An "Abbreviated" IDE: Check, if "Yes". If none of the criteria of Significant Risk (SR) Device Study in Section 3 is met, the study may be approved by the IRB, and not require an FDA IDE.

☐ Meets none of the above criteria in Section 3 ("Significant Risk (SR) Device Study").

If none of the criteria in Section 3 is met, briefly describe how the protocol-specific device and its planned research use meet NSR device criteria.

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