Investigational Device Exemption (IDE) EXEMPT DEVICE FORM

Principal Investigator:

Title of Study:

Device Name:

For IDE Exempt devices used in research, VU researchers must complete this form and attach it to the submission in the electronic IRB system. (Reference: *HRP-307 – Worksheet – Devices*)

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.)

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.[x]

☐ 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 noninvasive.[xi]

☐ 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 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

☐ 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.

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[x] 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.

[xi] 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