**Supplement Form M**

**Research Involving Medical Devices**

|  |  |
| --- | --- |
| **PI Name:** | **Date** |
| Title: | |

**I. Device Information**

1. This research involves the evaluation of the following type(s) of device (check all that apply and complete the appropriate sections below):

New investigational medical device

Approved device being used in accordance with its FDA-approved labeling

Investigational use of an FDA-approved device

1. Provide a plan for the storage, tracking, dispensing, handling, and disposal of the medical devices being evaluated in this research. Include storage location, security, and methods to segregate from general use product.

1. List all Investigational and FDA-approved medical devices evaluated in this research:

1. Out of the above, list any devices that are new investigational devices **or** that will be used for an indication, population, procedure, or other method that is outside of the FDA-approved labeling:

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **IDE?** | **If yes, IDE #** | **Holder of IDE** |
|  | Yes  No |  |  |
|  | Yes  No |  |  |
|  | Yes  No |  |  |
|  | Yes  No |  |  |
|  | Yes  No |  |  |

**II. IDE Evaluation**

The Investigational Device Exemptions (IDE) regulation ([21 CFR 812](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812)) describes three types of device studies: Significant risk (SR), Nonsignificant risk (NSR), and 812 Exempted studies. The category of device study determines which aspects of 21 CFR 812 the sponsor and researcher must comply with. This section of the form is intended to elucidate which device study category is appropriate for this study.

1. If the FDA has provided a device study category determination, please indicate the category here and include the letter from the FDA documenting the determination with your submission. If the study was determined to be Significant Risk, this documentation should include the IDE #.

NA, the FDA has not provided a determination

Significant Risk

Nonsignificant Risk

812 Exempt

1. If the FDA has not provided a determination, and this study is sponsored, the sponsor should provide an initial determination and justification for the IRB’s consideration. Please indicate the sponsor’s assessment here and include documentation from the sponsor with your submission.

NA, the study is not sponsored and the FDA has not provided a determination

Significant Risk

Nonsignificant Risk

812 Exempt

1. If this study does not have an external sponsor, and the FDA has not provided a determination, provide the investigator’s assessment of the proper categorization below and justification supporting the assessment. Information regarding device study categorization and links to relevant FDA regulations and guidance are provided in the Appendix at the end of this form.

NA, the FDA or sponsor have provided a determination

Significant Risk

Nonsignificant Risk

812 Exempt

Justification:

**Appendix I: Device Study Categories**

Under [21 CFR 812.3(m)](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.3), a Significant Risk (SR) device means an investigational device that:

* 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 use in supporting or sustaining human life and presents a 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 a potential for serious risk to the health, safety, or welfare of a subject; or
* Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

A SR device study is subject to the full requirements of [21 CFR 812](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812), including the need to submit an IDE application to FDA, and obtain approval, before the study can commence.

A Non-Significant Risk (NSR) device study is a device study that does not meet the definition of significant risk and does not qualify as an 812 exempted investigation. NSR device studies are subject to [abbreviated requirements](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.2) under 21 CFR 812. IRB approval of a NSR device study serves as the IDE approval.

812 exempted investigations include studies of the following categories of devices:

* Studies of an already cleared medical device in which the device is used or investigated in accordance with the indications in the cleared labeling.
* Studies of a PMA approved device if the device is being studied for the indications in the approved labeling.
* Diagnostic device studies (e.g., in vitro diagnostic studies) are exempt as long as the sponsor complies with the requirements at [21 CFR 809.10(c)](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=809.10) for labeling, and if the testing: (i) is [noninvasive](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.3); (ii) does not require an invasive sampling procedure that presents significant risk; (iii) does not by design or intention introduce energy into a subject; and (iv) is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

[21 CFR 812](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812), with the exception of [21 CFR 812.119](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.119), does not apply to exempted investigations.

**FDA Guidance:**

Investigators are encouraged to review the following FDA guidance documents:

[Frequently Asked Questions About Medical Devices](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf)

[Significant Risk and Nonsignificant Risk Medical Device Studies](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf)

[In Vitro Diagnostic Device (IVD) Studies – Frequently Asked Questions](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM071230.pdf)