MONTCLAIR
STATE UNIVERSITY

This document is a fillable PDF form. Please complete the application and either apply your electronic signature or print the document and sign. This document should then be uploaded to the appropriate section of your Cayuse submission.

DEVICE DECISION WORKSHEET

PI Name: _____ **Device Name:** _____

Protocol/Study Title & Number: _____

NOTE: The following worksheet is intended to help Montclair State University determine if a device application to the FDA may be required prior to initiating a new clinical study. This document should be completed for all of the device(s) utilized in your study, and then provided to the IRB via Cayuse in support of the application prior to initiating your study.

Investigational use of a device that is classified as Non-Significant Risk (NSR) may be approvable under the requirements provided all of the criteria are met (21 CFR 812.2).

Please answer all questions below:

DECISION CRITERIA	YES	NO	NOT SURE
1. Does the study involve a medical device that is being used in accordance with FDA approved labeling? **If NO,** then proceed to question #2. **If YES,** then an FDA approved IDE is not required.	☐	☐	☐
2. Is the medical device a diagnostic device? **If NO,** then proceed to question #4. **If YES,** then proceed to question #3.	☐	☐	☐
3. Answer all components (a-e) of question #3 below to determine if your diagnostic device is exempt. **NOTE** – A diagnostic device is considered exempt from IDE regulations *(21 CFR 812.2)* **ONLY** if **ALL** of the following statements are true:	☐	☐	☐
3.a. The diagnostic device complies with the labeling requirements of 21 CFR 809.10(c).	☐	☐	☐
3.b. The testing is non-invasive.	☐	☐	☐
3.c. The testing does not require any invasive sampling procedures that present a Significant Risk (SR).	☐	☐	☐
3.d. The testing does not by design or intention introduce energy into a subject.	☐	☐	☐
3.e. The testing is not used as a diagnostic procedure without confirmation of the diagnosis by another medically established diagnostic product or procedure.	☐	☐	☐
4. Answer all components (a-d) of question #4 below for **ALL** devices utilized in the clinical study to determine if any are Significant Risk (SR) devices. **NOTE** – An investigational device is classified as SR if **ANY** of the following statements are true *(21 CFR 812.3):*	☐	☐	☐
4.a. Is the investigational device intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject?	☐	☐	☐
4.b. Is the investigational device purported to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject?	☐	☐	☐
4.c. Is the investigational device for use in diagnosing, curing, mitigating, or treating a disease, or to prevent impairment of health and is a potential for serious risk to the health, safety or welfare of a subject?	☐	☐	☐

4.d Does the investigational device otherwise present a potential for serious risk to the health, safety or welfare of a subject?	☐	☐	☐

5. If **ANY** of the questions in #4 were answered **YES** (for any device utilized in the study), then that investigational device is **classified as SR and requires IDE from the FDA and approval from the IRB prior to study initiation.**

6. If **ALL** of the questions in #4 were answered **NO**, then the device(s) are **classified as NSR.** If the IRB agrees, then the investigator must comply with the 'Abbreviated Requirements' *(21 CFR 812.2)* and to the Protection of Human Subjects *(21 CFR 50)* and IRB regulations *(21 CFR 56)*.

X _____

Principal Investigator Signature

X _____

Date