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. The document should then be uploaded to the appropriate section of your Cayuse submission.

DEVICE DECISION WORKSHEET

PI Name: **Device Name:**

Protocol/ Study Title & IRB Number:

NOTE: This worksheet is intended to help Montclair State University determine whether an FDA device application may be required before initiating a new clinical study. The form must be completed for all devices used in the study and submitted to the IRB through Cayuse in support of the application before the study begins. **Only the Principal Investigator should complete and sign the form.** Please read the form carefully and answer only the questions applicable to your device.

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 below:

DECISION CRITERIA	YES	NO
1. Are the objectives of the investigation to study the safety and/or effectiveness of the device?	☐	☐

If "No" is selected for Question #1, the study is not subject to IDE regulations because the device is being used as a tool and is not the focus of the study. **Please do not complete any additional questions on the form and sign below.**

DECISION CRITERIA	YES	NO
2. Is the device FDA approved and being used per label?	☐	☐

If "Yes" is selected for Question #2, the study is exempt from IDE regulations. **Please do not complete any additional questions on the form and sign below.**

DECISION CRITERIA	YES	NO
3. Is the device being used for diagnostic purposes? *A diagnostic device is considered exempt from IDE regulations only if all of the following statements (3a–3d) are true, in accordance with 21 CFR 812.2.*	☐	☐
3a. The testing is non-invasive.	☐	☐

3b. The testing does not require any invasive sampling procedures that present a Significant Risk (SR).	☐	☐
3c. The testing does not by design introduce energy into a subject.	☐	☐
3d. The testing is not used as a diagnostic procedure without confirmation of the diagnosis by another medically established product or procedure.	☐	☐

If "Yes" is selected for all questions 3a through 3d, the study is exempt from IDE regulations. **Please do not complete any additional questions on the form and sign below.**

If "No" is selected for Question 3, the study is not exempt from IDE regulations because the device is not being used for diagnostic purposes and is instead intended to treat, cure, mitigate, or prevent a disease or condition.

DECISION CRITERIA	YES	NO
4. Is there a significant risk using the device? *An investigational device is classified as SR if **any** of the following statements (4a–4d) are true, in accordance with 21 CFR 812.3:*	☐	☐
4a. Is the investigational device intended as an implant and presents potential for serious risk to the health, safety, or welfare of a subject?	☐	☐
4b. Is the investigational device purported 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?	☐	☐
4c. 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?	☐	☐
4d. Does the investigational device otherwise present a potential for serious risk to the health, safety or welfare of a subject?	☐	☐

If **any** question in Section 4 is answered **"Yes"** for any device used in the study, the device is **classified as SR and requires a full IDE, including FDA and IRB approval**, before study initiation. If **ALL** questions are answered **"No,"** the device is **classified as NSR** and, if the IRB agrees with this determination, the investigator must comply with the abbreviated IDE requirements under 21 CFR 812.2, as well as the protections of human subjects and IRB regulations under 21 CFR 50 and 56.

X _____

Principal Investigator Signature

X _____

Date