MONTCLAIR STATE UNIVERSITY

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IDE DECISION WORKSHEET

For MSU Investigators / Medical Device Clinical Investigations

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

Protocol/Study Title & Number: _____

NOTE: The following worksheet is intended to help Montclair State University determine if an IDE 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 a clinical trial.

QUESTION: Does your study require an IDE, or does it meet ALL of the criteria for a Non-Significant Risk (NSR)?

Investigational use of a medical device that is classified as Non-Significant Risk (NSR) may be approvable under the abbreviated IDE requirements provided all of the criteria are met (21 CFR 812.2). **Please answer all questions below:**

IDE REQUIRMENTS 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 _____ X _____

Principal Investigator Signature **Date**