Avera

Institutional Review Board

Checklist: Devices

NUMBER	HRP-307

IRB Number:	
Protocol Title:	
Investigator:	

1.	**Device Applicability** (Check if "Yes". If any box in #1 is "Yes," continue with the rest of the checklist. Otherwise FDA IDE regulations do not apply, and you may be done with this checklist.)
☐	Does the activity involve the following? (**Check all that apply**) ☐ In the United States: The use of a device[1] in one or more persons that evaluates the safety or effectiveness of that device. ☐ Data regarding subjects or control subjects submitted to or held for inspection by FDA. ☐ Data regarding the use of a device on human specimens submitted to or held for inspection by FDA.
2.	**IDE Requirements** (Check if "Yes". One must be "Yes." If all are "No," the IDE information is not complete.)
☐	The device has an IDE. (Complete Sections 3 and 4)
☐	The device qualifies for an abbreviated IDE. (Complete Sections 4 and 5)
☐	The device is exempt from the IDE requirements. (Complete Section 7)
3.	**IDE Validation** (Check if "Yes". At least one must be "Yes." If all are "No," IDE Cannot be validated.)
☐	Sponsor protocol imprinted with the IDE number.
☐	Written communication from the sponsor documenting the IDE number.
☐	Written communication from the FDA documenting the IDE number. *(Required if the investigator or Avera holds the IDE.)*
4.	**IDE Device Control** (Check if "Yes". Must be "Yes." If "No," the information regarding device control is incomplete.)
☐	The plan for storage, control, and dispensing of the device is adequate to ensure that only authorized investigators will use the device and that they will use the device only in subjects who have provided consent. . (The investigator or other designated individual must maintain records of the product's delivery to the clinical trial site, the inventory at the site, the use by each subject, and the return to the Sponsor or alternative disposition of unused products. These records include dates, quantities, batch or serial numbers, and Expiration Dates (if applicable), and the unique code numbers assigned to the investigational products and trial subjects.
5.	**Abbreviated IDE** (Check if "Yes". All must be "Yes")
☐	The device is not banned by the FDA.
☐	The investigator will label the device in accordance with FDA regulations. (21 CFR §812.5)
☐	The IRB will approve the research under 21 CFR §50 and §56 and determine that the study is not a significant risk.
☐	The investigator will comply with FDA requirements for monitoring investigations. (21 CFR §821.46)
☐	The investigator will comply with FDA requirements for records and reports. (21 CFR §812.140, 21 CFR §812.150)
☐	The investigator will not market or promote the device. (21 CFR §812.7)
6.	**IDE Oversight for investigators who hold the IDE** (Check if "Yes". Must be "Yes" if the local investigator holds the IDE.)
☐	The local investigator has certified in writing that s/he will comply with FDA sponsor requirements (including GMP when applicable.)

[1] The term "device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

(1) Recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) Intended to affect the structure or any function of the body of many or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

7. 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.
☐	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.
☐	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 customer device as defined in 21 CFR 812.3(b) and is NOT being used to determine safety or effectiveness for commercial distribution.

Checklist completed by, and sign/date

Comments Section:

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Reviewer Name Sign, if possible Date