Appendix D: Use of Devices Investigator Checklist

Protocol title:

PI name: | Date:

Investigations with multiple devices must submit a separate form for each device.

Device name: _____

A device will **NOT** fall under the FDA regulations if all of the following statements are true:

1) Data will not be submitted to the FDA
2) Safety and/or effectiveness data will not be collected about the device
3) The device is used only as a tool to collect data to examine a physiologic principle

If ALL statements above are true, please initial here: _____

Please include this form and the device manual in your protocol submission to the IRB. No further information is required at this time.

This checklist serves as a guide to Sponsor-Investigators in determining and documenting information required by the IRB related to the use of a medical device which falls under the FDA regulations (21 CFR812) in a human subjects' research study and requires an Investigational Device Exemption (IDE). ***Sponsor-Investigator* is the individual who initiates and also conducts the regulatory requirements applicable to both sponsors and clinical investigators (21 CFR312.3).** A device will fall under the FDA regulations if data will be submitted to the FDA **OR** safety and/or effectiveness data are collected about the device.

The IDE regulations (21 CFR812) describe three types of device studies: significant risk (SR), which require an IDE application approved by the FDA, non-significant risk (NSR) which must follow the abbreviated IDE requirements (21 CFR812.2b) and do not require a submission of an IDE application to the FDA or exempt from IDE regulations (21 CFR812.2b30. Please consult the cited regulations for additional information on these types of device studies.

	For additional guidance, this flowchart may be helpful in determining if an IDE is required.			HRPP USE ONLY: Confirm information for IRB review, (based on protocol submission and checklist) noting a check mark ✔.
a.	Studies considered exempt from IDE regulations include:			
	• A legally marketed device when used in accordance with its' labeling.	☐ Yes	☐ No	
	• A diagnostic device if it complies with labeling in 809.10(c) and the testing is noninvasive, does not require an invasive sampling procedure that presents significant risk, does not by design or intention introduce energy into a subject, and is not used a diagnostic procedure without confirmation by another medically established diagnostic product or procedure.	☐ Yes	☐ No	
	• Consumer preference testing, testing of a modification or testing of a combination of devices if the device(s) have an approved Premarket Notification 510(k), or are exempt from 510(k) **AND** if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.	☐ Yes	☐ No	

	If "Yes" to one of the bulleted items, the study is exempt from IDE regulations. Please provide/attach supporting documentation, e.g., letter from the FDA, or other information used to make this exempt determination. This form is complete. If "No" to all bulleted items, continue to next item.			
b	Does the research collect safety and/or efficacy data on medical devices in human participants or on human specimens? (An IDE must be submitted to the FDA if the sponsor-investigator intends to conduct a clinical investigation with an investigational new device to determine safety and effectiveness **unless** the investigation is considered to have an approved application for an IDE, or is exempt from the IDE requirements. (21 CFR 812.2)	☐ Yes	☐ No	
c	Has the FDA assessed the device for a risk determination? If yes, Please indicate if the FDA determination is: NSR_____(non-significant risk) SR_____(significant risk) *If "yes", provide the IRB with a copy of the FDA documentation, and this form is complete, the remaining items do not apply.	*☐ Yes	☐ No	
d	Has the sponsor-investigator made a risk determination? If yes, Please indicate if the determination is: NSR_____(non-significant risk) SR_____(significant risk) Please provide the IRB with a description of the device, reports of prior investigations with the device, the proposed investigational plan, and any other information that will assist the IRB in the review of this determination.	☐ Yes	☐ No	
e	Please provide the plan to securely obtain store, dispense/use, and dispose of the device. Attach a separate document that includes this information or note the location/section/page # where this information may be found in the protocol			
f	The informed consent process/document must include a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained **and the possibility that the FDA may inspect the records.** (21 CFR 50.25 (a) (5))			
g	Is the study an applicable clinical trial? *"Applicable clinical trials" generally include:* *(1)* Trials of Drugs and Biologics*: Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation;* *(2)* Trials of Devices*: Controlled trials with health outcomes, other than small feasibility studies, and pediatric post-market surveillance.* *Complete statutory definitions and more detailed information on the NIH's current thinking about the meaning of "applicable clinical trials" may be found in the "Elaboration of Definitions of Responsible Party and Applicable Clinical Trial".* (if No, skip h)	☐ Yes	☐ No	
h	Is the clinical trial registered in Clinicaltrials.gov?	☐ Yes	☐ No	
	• Under federal regulation 21 CFR 50.25(c) the following statement must be reproduced word-for-word in informed consent documents for applicable clinical trials begun after March 7, 2012: "*A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time"*			
	Notes:			