Risk Determination - Devices
(Form date 5/2017)

Investigator:
Study Title:
IRB Number:

	Yes	No
1. Does the device qualify for an exemption from an IDE?		
• Exemption Category 21 CFR. 812.2(c)(3)? *If yes, proceed to review of protocol for submission for full board review:*		
1. Is non-invasive;		
2. Does not require an invasive sampling procedure that presents significant risk;		
3. Does not by design or intention introduce energy into a subject; and		
4. Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.		
• Exemption Category 21 CFR Sec. 812(c)(4) *if yes, proceed to review of protocol for submission for full board review.*		
1. Consumer preference testing;		
2. Testing of a modification; or		
3. Testing of a confirmation of two or more devices in commercial distribution.		
2. Is the investigator requesting a Humanitarian Use Device exemption? *If yes, proceed for full board review.*		
3. Is the investigator requesting an Emergency Exemption? Reference CHS CIRB policy *Emergency Use of a Test Article (Compassionate/Humanitarian Use)*		
• Has the investigator completed the Application/Report for the Emergency use of a Test Article?		
4. Is the device designated a 510(k) device by FDA? *If yes, proceed to full board review.*		
• Is the 510(k) letter included in the initial Submission Packet?		
5. Does the device have a Post Market Approval (PMA)? *If yes, proceed to full board review.*		
• Is the PMA letter included in the initial Submission Packet?		
6. Does the device have a FDA approved IDE? *If yes, proceed to full board review.*		
• Is there an application for an IDE? *If no, return submission to the*		

investigator with an explanation to resubmit when IDE approved.		
• Does the device have an unconditional approval from the FDA? *If yes, proceed to full board review.*		
	YES	NO
7. The sponsor/investigator has determined this to be a Non-significant risk device: *If yes, complete the following risk assessment.*		
• Does this appear to be a non-significant risk (NSR) device study?		
• Does the study device appear on the FDA list of SR devices? (Addendum I)		
• Is the device intended as an implant?		
• Does the device support or sustain human life?		
• Is the device's use of substantial importance in: diagnosing, curing, mitigating, or treating disease, or preventing impairment of health?		
• Could the investigational device cause significant harm to any subjects?		
• Must subjects undergo a procedure as part of the device study?		
• Would the subject undergo the procedure if they were not part of study?		
• Could the study or any of the study procedures cause harm the subjects?		
• Could the study procedures be life threatening?		
• Could the study procedures cause permanent impairment of a body function?		
• Could the study procedures cause permanent damage to body structure?		
• Could the study procedures necessitate medical or surgical intervention to:		
Preclude permanent impairment of a body function?		
Preclude permanent damage to body structure?		
Reviewer risk determination:		
Significant Risk		
Non-Significant Risk		

Comments:

_____ _____

Primary Reviewer Date