



Institutional Review Board
Checklist: Non-Significant Risk Device

NUMBER | HRP-418

IRB Number:	
Protocol Title:	
Investigator:	
1. Significant Risk Device Study (Check if "Yes". If any are check, the device is a significant risk device.)	
<input type="checkbox"/>	Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject.
<input type="checkbox"/>	Is purported or represented 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.
<input type="checkbox"/>	Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to health, safety, or welfare of a subject.
<input type="checkbox"/>	Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.
2. Non-Significant Risk Device Study (Check if "Yes")	
<input type="checkbox"/>	Meets none of the above criteria.
3. Rational (describe)	

I recommend the research be: (Please check one, and sign/date)

APPROVED

Approved with Conditions, Minor Clarifications and/or Modifications back to the IRB Office

Approved with Conditions, Major Clarifications and/or Modifications back to the Full (Convened) IRB Meeting

Do Not Recommend approval at this time. List Reasons. (*Convened board must agree by a vote if study is not approved.*)

Comments Section:

Print Name of reviewer Sign, if able Date