TEXAS A&M UNIVERSITY	**CHECKLIST:** Non-Significant Risk Device		
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The purpose of this checklist is to provide support for IRB members or the Designated Reviewer when research involves an abbreviated IDE. This checklist or its equivalent form or electronic equivalent must be used for all for reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.) [1]

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to the criteria for approval have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer or IRB staff attaches this checklist or equivalent to the to the protocol file.
- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to the criteria for approval have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB completes this checklist or equivalent form to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist or equivalent form to the protocol file or uses electronic equivalent.

IRB Number:	
Study Title:	
Short Title:	
Investigator:	
Device:	

1 SIGNIFICANT RISK DEVICE STUDY (If any are checked 'Yes', the device is a significant risk device.)

☐ **Yes** ☐ **No**	This device Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject.
If, **No**, provide detailed rationale in space below:	

☐ **Yes** ☐ **No**	This device 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.
If, **No**, provide detailed rationale in space below:	

☐ **Yes** ☐ **No**	This device 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 the health, safety, or welfare of a subject.
If, **No**, provide detailed rationale in space below:	

☐ **Yes** ☐ **No**	This device otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.
If, **No**, provide detailed rationale in space below:	

2 NON-SIGNIFICANT RISK DEVICE STUDY (Check if 'Yes".)

☐	Meets none of the above criteria for Significant Risk. All items above are checked 'No".

[1] This document satisfies AAHRPP elements II.5.A, II.5.B

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