

SIGNIFICANT and NON-SIGNIFICANT RISK CHECKLIST

Note: This checklist will be attached to all new protocols involving medical devices to assist in determining risk level and frequency of review

RR 402-C

01/01/07

STUDY NAME (IRB #): _____

IRB MEETING DATE: _____

Significant Risk Devices:

A significant risk device is an investigational device that:

_____ (1) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;

_____ (2) is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;

_____ (3) 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; or

_____ (4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

Non-Significant Risk Device:

_____ Non-significant risk devices are devices that do not post a significant risk to human subjects.

Approved 12/11/06

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