Non-Significant Risk (NSR) Determinations

Research Compliance Office

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What is a Medical Device – Brief Overview

An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is….

- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or
- intended to affect the structure or any function of the body, and which does not achieve its primary intended purposes through chemical action within or on the body ….

(FD&C Act; 21 USC 321(h))

Medical Device Studies – Brief Overview

Research that assesses the safety or effectiveness of a medical device must fall into one of the following categories:

- IDE Exempt
- Non-Significant Risk Device (NSR)
- Significant Risk Device

NSR Determinations – Brief Overview

A **non-significant risk** study must meet the following criteria:

- The medical device is **not** intended as an implant;
- The medical device is **not** purported or represented to be for a use in supporting or sustaining human life;
- The medical device is **not** of substantial importance in diagnosis, curing, mitigating or treating disease, or otherwise preventing impairment of human health;
- *And* the medical device does **not** present a potential for serious risk to the health, safety, or welfare of a subject.

Questions?