Quick Reference Guide for Device Determinations

What is a Medical Device?

A medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

· Recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
· Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
· Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes

Does it have an investigational device exeption (IDE)?	• FDA determined that the research proposed in the IDE application can proceed • **IRB Must: Receive a copy of the FDA IDE approval letter before the proposed research can proceed.**	IDE
Is the device exempt?	• Exempt from needing an IDE because it is a diagnostic device • **IRB Must: Confirm that the device is exempt from the requirement for an IDE because it is a diagnostic device**	Exempt
Is it a Non-Significant Risk Device (NSR/Abbreviated IDE)?	• The device as used in the study is not a significant risk device • **IRB Must: Explicitly determine that the device, as used in the study, is not a significant risk device**	NSR
Does it have Premarket Approval (PMA) or 510(k) Clearance?	• FDA determined that device is equivalent to a predicate device in use, safety, and effectiveness. • **IRB Must: Confirm that the device as used in the study is being used according to it cleared indication(s)**	Approved
Is it an Humanitarian Use Device?	• FDA determined that the device is safe and effective. • **IRB Must: Confirm that the device as used in the study is being used according to its approved indication(s)**	HUD

An exempt diagnostic device does not

- require an invasive procedure
- introduce energy into a subject
- used without confirmation of the diagnosis by medically established procedure.

A **NSR device** is not:

- intended as an implant;
- represented to be for use in supporting or sustaining life;
- of substantial importance in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of health;
- present a potential for serious risk to the health, safety or welfare of a subject

A HUD is an approved device. If used solely for treatment purposes, the use is not research but requires IRB approval. If used off label for research purposes, an IDE will be required.