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## IRB review of device studies

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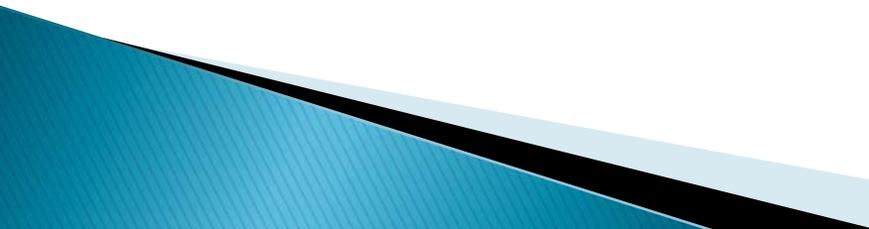
# IRB Review of Device Studies

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# What the IRB wants to know

- ▶ Is a device used in this study?
- ▶ If yes:
  - Is it approved?
  - Is it exempt?
  - What is the risk?
    - SR/NSR determination

# What do you mean I need an IDE I do this everyday....

- The practice of medicine
    - A class of activities designed solely to enhance the well being of an individual patient.
    - Not monitored by the IRB
    - Off label use of an approved device not subject to IRB oversight.
  - The conduct of research
    - a class of activities designed to develop or contribute to generalizable knowledge.
    - Different set of duties and obligations
    - Subject to IRB review and federal regulatory guidelines
- 

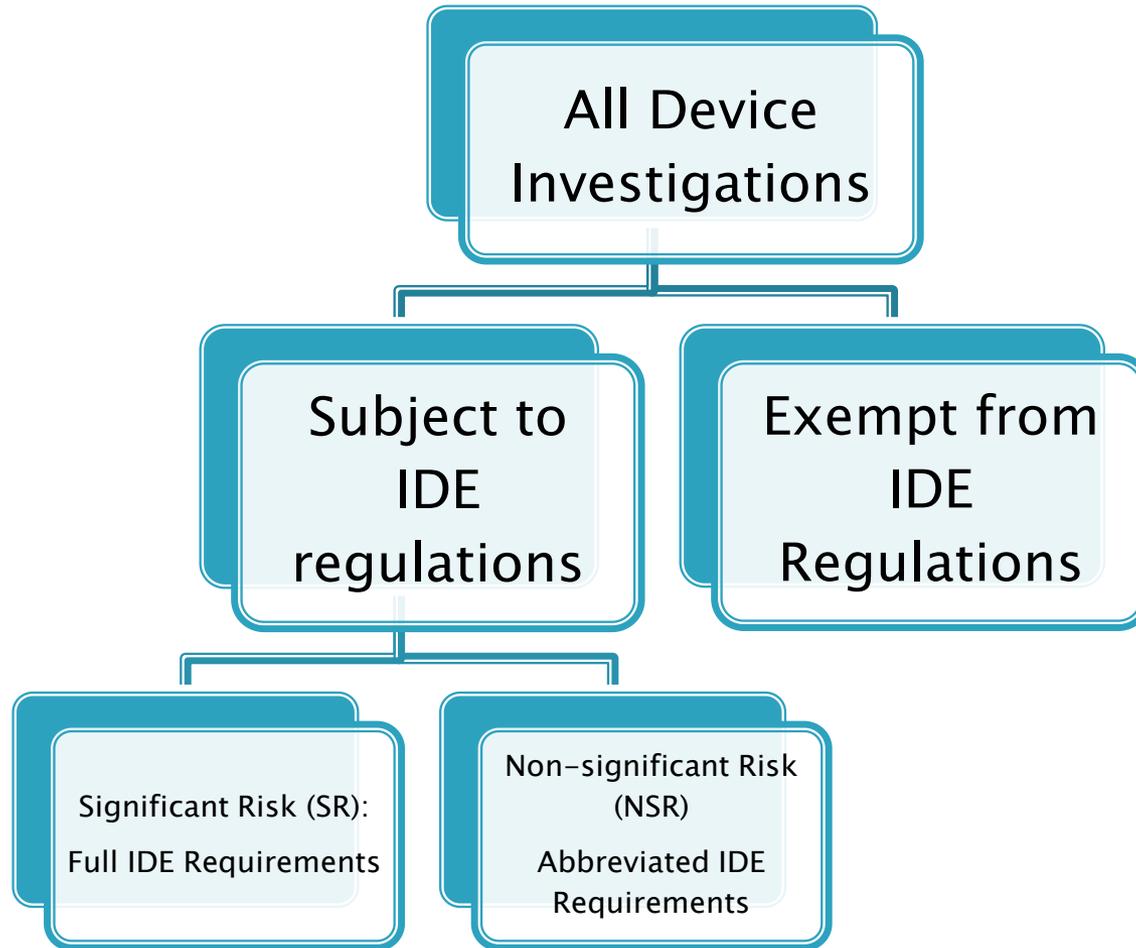
# Is there a device being used?

- 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 (21 U.S.C. 321(h)).

# Is the device investigational?

- ▶ If you are using the device in a clinical investigation, it is by definition investigational.
  - That does not mean it always needs an IDE
    - Might be exempt
    - Might be NSR (subject to abbreviated requirements)

# When do you need an IDE?



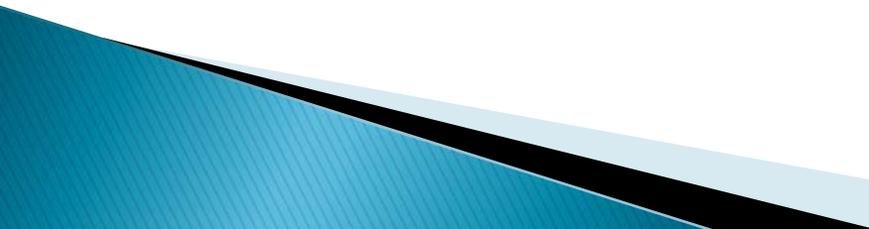
# When do you NOT need an IDE

- ▶ Practice of Medicine
  - Off label therapeutic use within the practitioner-patient relationship
- ▶ Basic Physiologic Research
  - Investigating a physiologic principle
  - No intent to develop for marketing
  - Only using to address the research question, not safety and effectiveness

# Is it exempt?

- ▶ Is it being used within its approved indication
    - Is the device modified at all?
    - How is it being used in the study?
    - What is on the PMA or 510(k) approval and how does that compare to the use you are proposing in your study
    - Does the use of the device in this study add risk to the subject?
- 

# Exempt studies: diagnostic devices

- A diagnostic device, if the sponsor complies with applicable requirements in 809.10(c) and if the testing:
    - Is noninvasive,
    - Does not require an invasive sampling procedure that presents significant risk,
    - Does not by design or intention introduce energy into a subject, and
    - Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.
- 

# Exempt studies

- ▶ A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness *and does not put subjects at risk.*

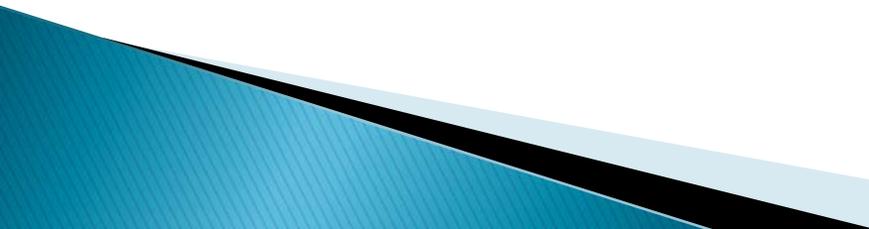
# Non-exempt

- ▶ Studies to support marketing application
  - ▶ Studies that will be submitted to the FDA
  - ▶ Studies of new indications
- 

# SR or NSR

- IRB must determine if:
  - Significant Risk: requires application to the FDA and assignment of IDE #, FDA reporting and monitoring requirements
  - Non-significant risk: abbreviated IDE requirements, IRB review, no application to the FDA
- NOT the same as the FDA class
- NOT the same as the minimal risk determination.

# Significant Risk Devices

- Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
  - 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;
  - 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
  - Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.
- 

# Non significant risk

- ▶ Everything else

# Who decides SR vs NSR

- ▶ If previously decided by the FDA, sponsor should provide the determination letter.
  - ▶ If no previous FDA decision, sponsor makes initial determination.
  - ▶ IRB must review and either agree or modify the sponsor determination if they disagree.
  - ▶ FDA is final arbiter if submitted.
- 

# Deciding Risk

- Review sponsor/PI information.
- What is the basis for the risk?
  - Proposed use of the device, not the device alone.
- What is the nature of the harm that may result?
  - Potential for serious risk to health, safety or welfare
- Are there any additional procedures with potential for harm?
  - Harm of the procedure should be considered, not just the device.

# Why bother.....

- ▶ Consequences of getting it wrong
    - You may have unnecessarily exposed the participants to risk.
    - Your study may get closed prior to completion.
    - You may not be allowed to use the data at all.
    - You will be conducting an investigation in violation of federal regulatory guidelines and may be subject to sanctions by the institution and/or federal agencies.
- 

# Emergency uses

- ▶ Emergency use of an unapproved device is permissible if:
  - The patient has a life-threatening condition that needs immediate treatment;
  - No generally acceptable alternative treatment for the condition exists; and
  - Because of the immediate need to use the device, here is no time to use existing procedures to get FDA approval

# Emergency Use

- ▶ IRB requirements
  - If time, you should submit a Form 11 to the IRB before the emergency use. If not, you must submit afterwards
  - If possible, informed consent should be obtained.
  - Obtain sponsor authorization
  - Independent physician assessment.

# Emergency use

- ▶ Must be reported to FDA and IRB w/in 5 days of use .
- ▶ IRB requires 30 day follow up

# Compassionate Use

- ▶ Appropriate if the investigational device is the only option available for a patient with a serious or life-threatening condition.
  - ▶ Differs from emergency use in that there is time to seek prior FDA and IRB approval, which is required for it to be used.
  - ▶ Specific monitoring and reporting requirements apply
- 

# Questions?

- ▶ We are available to help you with this process!