IRB Review of Medical Devices

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Six Steps to Ensuring Device Compliance

- Step 1: Is it a medical device, and is the medical device the focus of the study?
- Step 2: Is safety and/or efficacy data about the device collected?
- Step 3: Is the device approved and used according to approval?
- Step 4: Is the device exempt from the IDE regulations?
- Step 5: Is the device a significant risk device?
- Step 6: Non-significant risk determination

Step 1: Is it a medical device?

- Defined in 21 USC 321 (h)
- It is recognized in:
  - The official National Formulary
  - The US Pharmacopeia
  - Any supplement to the above
- It is intended for use in:
  - Diagnosing a disease or other condition
  - Curing, mitigating, treating, or preventing disease in man or other animals
- Intended to affect the structure or any function of the body
  - Does not achieve its primary purpose through chemical action and
  - Is not dependent on being metabolized to achieve its primary purpose

Step 1: Is it a medical device?

- Examples of some medical devices
  - Eye glasses
  - Gloves
  - Pacemakers
  - IV tubing
- Examples of some things which are not medical devices
  - FuelBand/FitBit to measure activity (not used to diagnose, cure, mitigate, or treat disease)
  - An app that allows a patient and physician to email securely
  - An app that allows a physician to distribute educational information about a disease or procedure to their patients

Step 2: Is safety and/or efficacy data about the device collected?

- Per 21 CFR 812.2(a)
  - The IDE regulations apply "to all clinical **investigations of devices** to determine safety and effectiveness"
- Per 21 CFR 812.3(g)
  - An investigational device is a device "**that is the object of an investigation**"
- Review the protocol to determine whether safety and/or efficacy of the device is being studied
- Ensure that the device's safety/efficacy is the objective/purpose of the study

Step 2: Is safety and/or efficacy data about the device collected?

- Examples of studies that would apply
  - Use of a new type of bandage to determine whether it is better at wound closure than stitches
  - Use of a new laser to determine whether it is safe to use in the treatment of acne
- Examples of studies which would not apply
  - Use of a FitBit to collect heart rate data during a subject's participation in a marathon
  - Use of an approved diagnostic test for sickle cell disease to determine entry into a study for sickle cell patients.

Step 3: Is the device approved and used according to approval?

What counts as “approved”?

- 510 K Exempt
  - All Class I devices and all class II devices which appear on the FDA’s published list.
  - Rarely seen at Full Committee level
- 510 K Cleared
  - Clinical trials not required to be conducted to obtain this status
  - PI should indicate device is approved and used according to approved label in the IRA
  - PI should provide evidence of 510 K clearance in submission
- Pre-Market Approval (PMA)
  - FDA approval after clinical trials have been completed
  - PI should indicate device is approved and used according to approved label in the IRA
  - PI should provide evidence of approval in submission
- Humanitarian Use Device
  - A device intended to treat or diagnose less than 8,000 patients per year
  - Use is not considered research, but IRB review is required
  - PI should indicate that the device is a humanitarian use device in the IRA

Step 3: Is the device approved and used according to approval?

- If the device is approved, is it used according to its approval?
- Review Indications For Use or device label
- If not used according to approved indications, proceed to next step

- Examples of off-label use
  - An implant approved for spinal infusion used for infusion in the liver
  - A test approved to detect a specific pathogen used to detect other pathogens
  - A laser approved to treat acne used for hair removal

Step 4: Is the device exempt from the IDE regulations?

- Exempt devices do not require an IDE
- Per 21 CFR 812.2(c)
  - Devices in distribution prior to May 28, 1976
    - Iron lung – 1929
    - Modern scalpel – 1915
    - Hypodermic needle – 1954
  - Devices which are substantially equivalent to devices in distribution prior to May 28, 1976
  - Diagnostic devices when:
    - They are noninvasive
    - Do not require an invasive sampling procedure which presents significant risk
    - Do not introduce energy into a subject
    - Are not used without confirmation by a medically established diagnostic
    - E.g. A new blood test for sepsis when a traditional blood culture is also used
- See HRP-307 Section 6 and/or HRP-418 Section 3

Step 5: Is the device a significant risk device?

- If not exempt, the IRB determines if the device is a significant risk device
- Significant Risk Device criteria:
  - Must present the potential for serious risk to the subject
  - May be intended as an implant
  - May be for a use in supporting or sustaining human life
  - May be for substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health

Step 5: Is the device a significant risk device?

- Examples of significant risk devices
  - Pacemakers
  - Defibrillators
  - Surgical lasers
  - Collagen implants

- See HRP-418 Section 1

- If the device does meet these criteria, an IDE is required
- If the device doesn't meet criteria, proceed to next step

Step 6: Non-significant risk determination

- A non-exempt investigational device which does not meet the Significant Risk Device criteria is considered a Non-Significant Risk device
  - See HRP-418 Section 2
- The IRB is required to make this determination
- Does not require an IDE from the FDA
  - Is granted an abbreviated IDE upon IRB determination and approval
- Must still abide by FDA requirements at 21 CFR 812.2(b)(1)

QUESTIONS?