Medical Devices
IRB Determination

IRB Member Continuing Education

AAHRRP Element II.2. D.

- Element II.2.D. The IRB or Ethics Committee has and follows written policies and procedures to conduct reviews by the convened IRB or Ethics Committee.
- 1. Element II.2.D.1. – Initial review
- 2. Element II.2.D.2. – Continuing review
- 3. Element II.2.D.3. – Review of proposed modifications to previously approved research

HRPP 2.5
Convened Meetings of the IRB

- The rationale for significant risk/non-significant risk device determinations; ***or the device is exempt from the IDE regulations.***

Three Basic Things

1. Does the study involve a device?
2. Is the devise SR or NSR?
3. Does the study need and IDE?

Definition of Medical Device

- An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent…a component, part o, or accessory….intended for a diagnosis of disease or condition or cure, mitigation, treatment, or prevention of disease or affects the structure or function of the body…and does not achieve primary purpose through chemical action…or being metabolized.

Significant Risk Device

Presents a potential for serious risk to the health, safety or welfare of a subject. SR devices my include implants, devices that support or sustain human life, and devices that are substantially important in diagnosing, curing, mitigating or treating disease or in preventing impairment to human health.

How to Obtain IDE for a Study Using a Significant Risk Device

- Sponsor submits IDE application to FDA
- FDA approves or disapproves
- After FDA approval and IRB approval the study can begin

Non-Significant Risk (NSR) Device

- A device that is no significant risk.

  Examples: externally worn monitors for insulin reactions, gastroenterology and urology endoscopes and/or accessories, etc.

IDE for a Study Using Non-Significant Risk Device

- Sponsor presents the IRB with protocol and a brief explanation why the device is not a significant risk device. And, any other information requested by the IRB.
- If the IRB determines the device is NSR and approves the study – the study is considered to have and approved application for IDE
- No formal IDE submission to FDA

NSR Device Studies
IRB Responsibilities

- Review definitions
- Review Sponsor's brief explanation of why the devices is NSR and not SR
- Conduct literature search
- Search Internet
- Ask FDA for assistance

Making the Risk Determination

- What is the basis for the risk?
  - Proposed use of device
- What is the nature of harm that may result from the use of the device
- Any additional procedures
  - Potential harm from procedures
- Consider how the device is used in the study and not the device alone.

Exempt Studies (exempt from 21 CFR 812) No IDE Needed

- Description of exempt devices [(21 CFR 812.2(c)]
  - -approved devices used in accordance with labeling
  - -most in vitro diagnostic devices (IVDs)
  - -consumer preference testing
  - -testing of minor modification
  - -testing of a combination of approved devices

- FDA post approval studies

IRB Responsibilities

- IRB's should make the SR or NSR determination at a convened meeting.
- IRB should document its SR/NSR determination in the IRB meeting minutes.
- Maintain all other documentation.