HUD and Emergent Use

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Device Classification

- Significant risk
  - Often involve an invasive procedure for implantation or use
  - Requires IDE consideration
- Non-significant risk (NSR) devices
  - Requires only IRB protocol approval

- Investigational New Device:
  - A device permitted by the FDA to be tested in humans but not yet determined to be safe and effective for a not yet licensed. This includes devices already approved for other indications
- Investigational Device Exemption (IDE):
  - veterinary
  - diagnostic device, if the testing:
    - Is noninvasive.
    - Does not require an invasive sampling procedure that presents significant risk.
    - Does not by introduce energy into a subject.

Humanitarian Use Device (HUD)

- 21 CFR 814.3(n)
- Created by 1990 Law
- For diseases with <4000 people/year in US
- Sponsor files a humanitarian device exemption (HDE) with FDA
- Issue “orphan subset” of common disease
  - Unmet medical need is not sufficient rationale

Regulatory Status

- HUD use not research
- Only circumstance where IRB has clearly defined oversight of non-research activity
- HDE does not expire so long as device continues to meet requirements
- IRB does require periodic review

IRB review

TJU Policy SC 503

- Initial Review could
  - approve the use of the device without any restrictions, OR
  - use of the device under protocol, OR
  - use of the device on a case-by –case basis on a protocol basis
- Continuing Review
  - expedited review

Consent

- IRB will make a determination as to whether it would be prudent to require a consent form,
- IRB may require that both the investigator and the subject sign the Device Brochure
- Investigator must agree that use is not part of research project or study designed to collect data to support an FDA pre-market approval application

Emergent Use of Devices

- Emergency use; not sufficient time to obtain IRB approval [(21CFR56.102(d)].
- Reported to the IRB within 5 working days after its initiation/administration.
- Any subsequent use of the test article must have prior review by the full IRB (21 CFR 56.104)..

Emergent and Emergency Uses of Drug or Device

Emergency uses must meet ALL criteria:

- disease is life threatening or severely debilitating
- no generally acceptable alternative for treatment is available
- requires intervention with the investigational drug or biologic before review at a convened IRB meeting

Investigator Responsibilities

- independent assessment of necessity by an uninvolved physician
- informed consent from the participant or participant's legally authorized representative
- documenting consent
- notify the Institutional Review Board (IRB)

- Evaluate the likelihood of a similar need for recurring use of the test article,
- Consider IRB approval, or IND or IDE for subsequent use.
- Repeated use of emergent use not appropriate