Investigational and Marketed Devices (HRPP 6.2)

Description:

This policy describes UNMC's requirements for research involving investigational and marketed drugs.

Definitions:

Investigational Device: a device, including transitional device, which is the object of the clinical investigation. A device is any healthcare product that does not achieve its primary intended purpose by a chemical action or by being metabolized.

Significant Risk Device (SRD): a medical device that:

- Is implanted and presents potential for serious risk to the health, safety, or welfare of the subject; or
- Is being used in support of sustaining human life and presents potential for serious risk to the health, safety, or welfare of the subject; or
- Is used for diagnosing, curing, mitigating, or treating disease otherwise preventing impairment of human health and presents potential for serious risk to the health, safety, or welfare of the subject; or
- Otherwise presents potential for serious risk to the health, safety, or welfare of the subject; or

NOTE: these studies must follow strict FDA rules and need an IDE before starting.

Non-significant Risk Device (NSRD): a device that is not an SRD.

NOTE: these studies must still follow abbreviated requirements but there is no need to make reports to the FDA and they don't have to have an Ide application approached by the FDA.

Investigational New Device Exemption (IDE): an application submitted to the FDA to conduct a clinical investigation with an investigational device and is classified as an SRD.

Marketed Device: a medical device that has already been approved by the FDA for marketing and is being used to treat and/or diagnose patients.

Custom Device: a device that meets **all** of the following criteria:

- Different from generally available devices or performance standards to meet the order of an individual physician or dentist
- Are not available or used by other physicians or dentists,
- Aren't available for purchase or dispensing,
- Aren't offered for commercial distribution, and
- Are intended for use by an individual patient, or to meet the needs of an individual physician or dentist

Study Requirements:

- Before any study involving an investigational device can begin, contracts between the sponsor and the organization must be reviewed and approved by special offices:
  - **UNMC, NM, and BMC:** reviewed by UNMC Sponsored Programs Administration (SPA) or UNeHealth
  - **Children's Nebraska:** reviewed by UNMC SPA, UNeHealth, or by Nebraska Children's Administration
- If a device poses a **serious risk** (SR), the study must be reviewed by the full IRB
  - If the device is **low risk** (NSR) or exempt, the IRB may approve through an expedited review process
- If the contract requires compliance with *(ICH-GCP),* the investigator will designate this in the IRB application and the IRB will make sure the study plan complies with HRPP Policy 1.13
- If the study involves an investigator-initiated IDE, the PI must also take responsibility for following FDA sponsor rules and submit a form *(Addendum P)* confirming they understand their duties
- If a study is being audited by a sponsor, a CRO, or the FDA, the PI must immediately inform the IRB and the UNMC Chief Compliance Officer and provide a report afterward
- If the study is audited by the Fred & Pamela Buffett Cancer Center Protocol Review Monitoring System (PRMS) Audit Committee, a copy of the report must be provided to the IRB

IRB Review Procedures:

- The **IRB checks to make sure:**
  - The device has FDA approval to be studied (IDE) or qualifies for exemption
  - The device is not banned
- The IRB make sure the PI has a **secure process for storage, security, and dispensing of the device.** The IRB will assess whether:
  - Device is stored and secured in a manner restricting access to investigators
  - Device is dispensed in a manner that assures that only subjects who've provided consent will be treated or tested/examined using the device
    - Should involve marking the device as *"investigational use only"*
  - Investigator and departments, sections, or operating rooms where the device is used must maintain sufficient records including where the device came from, who used it, what happened to it, etc.
- The IRB **will review the sponsor's determination of risk classification** of the device and make a determination based on:
  - The potential harm associated with the device itself
  - The proposed use of the device
  - Any procedure necessary for implantation of the device
  - A comparison of the risks of the device against the risks of alternative devices or procedures

  NOTE: if the IRB calls the device SR and the sponsor had called it NSR, the sponsor must report the IRB's decision to the FDA within 5 business days after learning of the determination. The IRB retains the ultimate authority in deciding whether or not to accept FDA's NSR classification.

- **If the device is NSR:** no FDA IDE application required, but the sponsor and PI must still follow abbreviated rules *(labeling, IRB approval, informed consent, monitoring, records, reports, and prohibition against promotion)*
- **If the device is SR:** FDA must approve the IDE and the IRB needs written proof before final approval
- For studies involving marketed SRDs for potential new indications, the IRB may require submission of an IDE application

When IDE is NOT Required (Exemptions):

Any of the following types of clinical investigations are exempt from IDE requirements:

- Clinical investigations using approved devices exactly in accordance with its labeling
- Use of in vitro devices, if the sponsor complies with applicable labeling requirements and if the testing:
    - Is noninvasive; and
    - Doesn't require an invasive sampling procedure presenting significant risk; and
    - Doesn't introduce energy into a subject; and
    - Isn't used as a diagnostic procedure without confirmation by another, medically established diagnostic product or procedure
- Use of a marketed device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, unless testing is for determining safety and efficacy and/or puts subjects at risk
- Use of a custom device, unless the device is being used to determine safety or effectiveness for commercial distribution

NOTE: exemption from IDE regulations does NOT mean exempt from IRB review