

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 a 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 device that:

- Is intended as an implant and presents potential for serious risk to the health, safety, or welfare of the subject; or
- Is believed or represented to be for a use in supporting or sustaining human life and presents potential for serious risk to the health, safety or welfare of the subject; or
- Is for a use of substantial importance in 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.
- *SRD studies must follow all IDE regulations at 21 CFR 812 and must have an IDE application approved by the FDA before they may proceed.*

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

- *Must follow abbreviated requirements at 21 CFR 812.2(b)*
- *There is no need to make progress reports or final reports to the FDA.*
- *Does not 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 subject to 21 CFR 812.2 and is classified as an SRD.

Marketed Device: a device approved by the FDA for marketing and is generally in use for treatment and diagnostic purposes.

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
- Not generally available to, or used by, other physicians or dentists
- Not generally available for purchase or dispensing upon prescription
- Not offered for commercial distribution
- Intended for use by an individual patient, or to meet the needs of the individual physician or dentist

IRB Review/Assessment:

- All contracts between sponsors and **UNMC, NM, and BMC** for investigational drug studies must be reviewed and approved by UNMC Sponsored Programs Administration (SPA) or UNeHealth.
- All contracts between sponsors and **Nebraska Children** for investigational drug studies must be reviewed and approved by UNMC SPA, UNeHealth, or by Nebraska Childrens Administration.
 - If reviewed by Nebraska Childrens Administration, must ALSO be reviewed by UNMC SPA.

The IRB will review and assess the following:

- **Storage, security, and dispensing of the investigational device:**
 - The device must be stored and secured in a manner restricting access to investigators.
 - The device must be dispensed in a manner that assures that only subjects who have provided informed consent will be treated or tested/examined using the investigational device.
 - The investigator and departments, sections, or operating rooms where the device is used must maintain sufficient records.
- The sponsor's **determination of risk classification** of the device and make the determination based on:
 - Potential harm associated with the device itself
 - Proposed use of the device
 - Implantation procedure
 - Comparison of the risks of the device to the risks of alternative devices or procedures

General Requirements:

- Clinical investigations involving SRDs must be reviewed and approved by the full IRB.
 - Clinical investigations involving NSRDs and exempt devices that are no more than minimal risk may be eligible for expedited review.
- If the contract agreement requires compliance with ICH GCP, the IRB will review the submission in accordance with its policy.

- If a study involves an investigator-initiated IDE, the PI will also comply with the FDA-mandated sponsor requirements (21 CFR 812) and certify compliance by submitting Addendum P in the application.
- Any PI who has a study audited by the sponsor, a CRO or FDA must immediately notify the UNMC Chief Compliance Officer and provide a report to the IRB.

When the study is audited by the Fred & Pamela Buffett Cancer Center Protocol Review Monitoring System (PRMS) Audit Committee, a report must be provided to the IRB.

Exemption from IDE Requirements:

The **following types of clinical investigations are exempt:**

- Use of **approved devices used in accordance with its labeling.**
- Use of **in vitro devices, if the sponsor complies with applicable labeling requirements 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.
 - Is not used as a diagnostic procedure without confirmation of the diagnosis 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 2 or more devices in commercial distribution**, unless testing is for determining the 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.