Investigational and Marketed Drugs (HRPP 6.1)

Description:

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

Procedures:

- 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 **Children's Nebraska** for investigational drug studies must be **reviewed and approved by UNMC SPA, UNEHealth, or by Children's Nebraska Administration**
- If a contract says the study must follow international research rules (ICH-GCP), the IRB will make sure it does
- The investigator will make sure all study drugs are safely stored and dispensed according to local institutional policies
- 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
- The PI must inform the IRB and Investigational Drug Pharmacist if a study involving an investigational drug is terminated

Studies Requiring an IND:

- Before a new drug can be tested in a study, the IRB must confirm the FDA has given permission through an IND
- If a study involves an investigator-initiated IND, the PI must comply with FDA-mandated sponsor requirements and certify compliance by submitting Addendum O (in the IRB application)
- If a study involves a marketed drug for potential new indications or changes in dose, an IND is required

When You Do NOT Need an IND:

- **Drug is lawfully marketed (already approved):** *no IND needed if:*
    - The investigation isn't intended to report a new use or any other significant change in labeling of the drug
    - The investigation won't change how the drug is advertised
    - The investigation doesn't involve any factors that significantly increases the risks associated with the drug
    - All FDA and ethical rules are still followed

Using Investigational Drugs for Treatment (Expanded Access):

- **Who Can Get Expanded Access**
    - People who aren't enrolled in a clinical trial may still access an investigational drug if:
        - They have a serious or life-threatening disease or condition
        - No comparable or satisfactory alternative therapy to diagnose, monitor, or treat
        - The drug's potential benefit outweighs/justifies the risks
        - Providing the investigational drug for the requested use won't interfere with ongoing clinical investigations
- **All Expanded Access Programs Need:**
    - IRB review (or IRB Chair concurrence for single patients)
    - Informed consent from the patient (unless emergency situation- see HRPP Policy 6.5)

Using Investigational Drugs in Emergency Situations:

- When a drug is used in an emergency situation, it must be administered to subjects in accordance with HRPP Policy 6.4