Placebos (HRPP 3.13)

Description:

This policy describes UNMC's requirements for IRB review and approval of clinical trials that utilize placebos.

Definitions:

Placebo: an inactive substance or treatment that may resemble an active medication or treatment but has no therapeutic value.

Randomization: assignment of subjects to different treatments, interventions, or conditions according to chance rather than systematically.

Use of a Placebo:

Use of a placebo is ethically justified if:

- There is no standard therapy.
- Standard therapy is known not to be effective (it's no better than no treatment).
- Standard therapy may be effective but is associated with significant toxicity.
- Standard treatment is unavailable.
- There are scientifically sound reasons to use a placebo and patients who receive it will not be subject to additional risks as a result of not receiving the intervention.

Informed Consent Requirements:

For **clinical trials using a placebo**, the informed consent process and document must include:

- A statement that a placebo is used in the study and an appropriate lay definition of placebo.
- The scientific rationale for the use of a placebo.
- The risks of non-treatment associated with a placebo, including worsening of the subject's disease or condition.
- The plan for early withdrawal from the study if the subject's clinical status worsens or fails to improve to a pre-defined level.