Placebos (HRPP 3.13)

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

Definitions:

<table>
<thead>
<tr>
<th>Definition</th>
<th>Description</th>
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<td>Placebo</td>
<td>An inactive substance or treatment that may resemble an active medication or treatment but has no therapeutic value.</td>
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<td>Randomization</td>
<td>Assignment of subjects to different treatments, interventions, or conditions according to chance rather than systematically.</td>
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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.