Wash-Out (HRPP 3.13)

Description:

This policy describes UNMC's requirements for IRB review and approval of clinical trials that utilize wash-out effective therapy.

Definitions:

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

Wash-Out Period: a protocol required period of withdrawal from current treatment prior to initiation of placebo or active treatment arms.

Use of a Wash-Out:

Use of a wash-out is ethically justified if:

- There are scientifically sound reasons for the wash-out and subjects will not be placed at additional risks of serious or irreversible harm during the wash-out period.

Informed Consent Requirements:

For **clinical trials utilizing wash-out of effective therapy**, the informed consent process and document must include:

- A statement that the research will utilize a wash-out period and an appropriate lay definition of it.
- The scientific rationale for a wash-out period.
- The risks of the wash-out period, including worsening of the subject's disease or condition.
- The plan for early termination of the wash-out and resumption of the effective therapy if the subject's clinical status worsens.