Waiving Consent Process (HRPP 5.2)

Description:

This policy describes UNMC's requirements for granting a waiver or alternation of informed consent with or without waiver of HIPAA authorization in research.

Criteria for a Waiver or Alteration of Consent:

- Minimal risk
- Research could not practicably be carried out without the waiver/alteration. Examples:
  - Sample size required is too large.
  - Subjects lost to follow-up.
  - Disclosure of study purpose would create bias.
  - Risk of creating additional threats to privacy by having to link otherwise deidentified data.
  - There is a risk of inflicting psychological, social, or other harm.
- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.
- The waiver or alteration would not adversely affect the rights and welfare of subjects.
- The subject or LAR will be provided with additional pertinent information after participation, if appropriate.

Criteria for a Waiver of Parent/Guardian Consent (Permission):

- The research is designed for which parent/guardian consent/permission is not a reasonable requirement to protect the subjects:
  - Informing parents/guardians may result in harm to the child.
  - The research is important to the health and wellbeing of adolescents and the subjects can understand informed consent at an adult level.
  - An appropriate mechanism is in place for protecting the children who will participate.

Criteria for a Waiver or Alteration of Consent for FDA Regulated Research:

- Minimal risk
- Will not adversely affect the rights and welfare of subjects.
- The clinical investigation cannot practicably be carried out without the waiver/alteration.
- Subjects are provided with additional pertinent information after participation (when appropriate).

Criteria for a Wavier or Alteration of Consent for Research with Prisoners:

A complete waiver of consent for research involving prisoners is NOT permitted.