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 Waiver/Alteration of Consent:

- **Minimal Risk to Subjects**
- Research could not practicably be carried out without the waiver/alteration. Examples:
  - Required sample size 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
  - Risk of inflicting psychological, social, or other harm
  - **NOTE**: Inconvenience or cost is NOT a valid reason
- if the research involves identifiable private information or biospecimens, the research could not practicably be carried out without using the information or biospecimens in an identifiable format
- the waiver/alteration would not adversely affect the rights and welfare of subjects
- the subject or LAR will be provided additional pertinent information after participation, if appropriate

Criteria for Waiver of Parental/Guardian Consent (Permission):

- **Parental Permission Not Reasonable**
  - May cause harm to subject *(e.g. in STD studies)*
  - 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 to protect the children participating

Criteria for Waiver for Public Benefit/Service Program Research:

- Conducted by or subject to approval of state or local government officials
- The research is designed to study, evaluate, or examine:
    - Public benefit or service programs
    - Procedures for obtaining benefits or services under those programs
    - Possible changes in or alternatives to those programs or procedures
    - Possible changes in methods or levels of payment for benefits or services under those programs
- Impracticable without the waiver
- NOT FDA regulated

Criteria for Waiver for FDA-Regulated Minimal Risk Research

- **Minimal Risk;**
- Impracticable without the waiver;
- If the research involves using identifiable private information/biospecimens, it could not practicably be carried out without using the information/biospecimens in an identifiable format;
- No adverse effect on rights and welfare of the subjects; and
- When appropriate, the subjects/LARs are provided with additional pertinent information after participation

Waiver of Consent for Prisoner Research:

Complete waiver of informed consent is NOT allowed.