Waiving Signed Consent (HRPP 5.4)

Description:

This policy describes UNMC's process for IRB waiver of the requirement to obtain a signed consent form .

Criteria for IRB Approval of a Waiver:

The IRB may waive the requirement if it finds **any of the following are true**:

- **The only record linking the subject and the research would be the consent form and the principal risk would be a breach of confidentiality.**
  - Applies only to NON-FDA REGULATED RESEARCH.
  - The subject (or LAR) will be asked whether the subject wants documentation linking the subject to the research.
  - Oral or written information provided to subjects includes all the required and additional elements of consent.
- **The research is minimal risk and involves no procedures for which written consent is normally required outside of the research context.**
  - For NON-FDA REGULATED research: no additional requirements.
  - For FDA REGULATED research: the subject will be provided a written statement regarding the research (ex. ICF without signature blanks, a narrative consent form, etc.).
- **The subject (or LAR) is a member of a distinct cultural group or community in which signing forms is not the norm.**
  - Applies only to NON-FDA REGULATED RESEARCH.
  - Research must be minimal risk.
  - An appropriate alternative mechanism for documenting that informed consent was obtained must be applied.

Process of Review:

1) The investigator completes and submits the appropriate sections of the IRB application requesting the waiver.
2) The IRB reviews the proposed request.
3) Documentation and justification for IRB approval of the waiver will appear in the IRB review letter.