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 of Signed ICF:

The IRB may waive the requirement for obtaining a signed ICF for some or all subjects **if any of the following are true:**

- **The only record linking the subject to the research is the signed consent form**
  - Applies only to NON-FDA REGULATED RESEARCH
  - The subject/LAR will be asked whether the subject wants documentation linking the subject to the research
  - Oral or written information provided to subjects includes all required and additional elements of consent
- **The research is normally minimal risk and involves no procedures for which written consent is normally required outside of research**
  - No additional requirements for NON-FDA REGULATED RESEARCH
  - **For FDA-REGULATED RESEARCH:** the subject will be provided a written statement regarding the research *(e.g. ICF without signature blanks, a narrative consent form)*
- **Subject/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