Change Requests (HRPP 2.4)

Description:

This policy describes UNMC's requirements for IRB review of changes in previously approved research, including single subject protocol deviations.

Definitions:

Major Change in Protocol: a change that adversely affects the risk-benefit relationship by adding increasing risks, decreasing potential benefits, or impacts the process of consent in a manner that might affect a reasonable person's willingness to participate.

Minor Change in Protocol: a change that does NOT adversely affect the risk-benefit relationship by adding increasing risks, decreasing potential benefits, or impact the process of consent in a manner that might affect a reasonable person's willingness to participate.

Single Subject Protocol Deviation: a change permitted for an individual subject when it is in the best interest of that subject and/or is necessary for research purposes. These are submitted and approved BEFORE the change is implemented.

Administrative Change: a change where ONE of the following criteria is met:

- The proposed change has no impact on human subject protection
- The proposed change is necessary to clarify or provide only editorial updates to the protocol and/or informed consent form (ICF)

Examples: changes in telephone numbers, changes of study personnel, correction of typographical errors.

Change Request Procedures:

1) A Change Request is submitted in RSS.
2) The Change Request is reviewed by an IRB Analyst or the ORA staff.
3) The Change Request is labeled and processed accordingly:
    a. *Administrative change*- processed by the ORA.
    b. *Minor change*- processed by the IRB Executive Chair or designee.
    c. *Major change*- processed by the full IRB.

Single Subject Protocol Deviation Procedures:

1) A Single Subject Deviation request is submitted in RSS.
2) If applicable, approval from the study sponsor must be requested prior to submitting a request in RSS.
3) **If the change is more than minor**, it must be referred to the full IRB for review and approval prior to initiating the change.
4) If the change is minor, it must be reviewed and approved by the IRB Executive Chair, IRB Chair, or designee prior to initiating the change.

General Considerations:

The date of continuing review does not change based on the change request approval dates.

Any proposed changes in research MUST be approved by the IRB or ORA prior to implementation except in the circumstances listed below.

Changes that do not need IRB approval prior to implementation:

Changes may be implemented **without IRB approval only when**:

- A change is necessary to eliminate an immediate hazard to the subject(s), or
- A subject needs to be advised immediately of significant new information
    - No new subjects may be accrued without IRB approval of the new ICF.
    - If the change is not eligible for expedited review, it will be reviewed at the earliest possible IRB meeting.

If this occurs, the ORA must be notified **no later than 2 business days** from when the change was initiated.

- If the change was for ALL subjects, a change request must be submitted.
- If the change was for a SINGLE subject, a single subject protocol deviation request must be submitted.

Exempt Research Change Requests:

Change requests for exempt research do not need to be submitted provided the changes do not:

- Affect the risk-benefit relationship
- Post new risks that are greater than minimal
- Create new risks to privacy or confidentiality
- Involve sensitive topics
- Involve deception
- Target a vulnerable population
- Include prisoners
- Include children
- Otherwise suggest loss of exempt status of research