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 could:

- Add increased risks, or
- Decrease potential benefits, or
- Change how the study is explained in a way that might make someone decide not to join

Examples: Changing a medication dose in a way that increases side effects, or removing important information from the consent form

Minor Change in Protocol: a change that is not serious and does not significantly affect risks, benefits, or the consent process.

Examples: slight wording changes in a questionnaire or adding a study visit that involves only a routine check-up.

Single Subject Protocol Deviation (SSPD): a **one-time change for a single participant**, usually to:

- Help that specific person
- Adjust for special research needs

These are submitted and approved BEFORE the change is implemented.

Administrative Change: a technical or paperwork change that has no effect on participants' health, safety, or understanding of the study.

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.

Change Request Procedures:

1) A change request is submitted in RSS
2) The change request is reviewed by the IRB or ORA
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 a designee
    c. *Major Change*- processed by the convened board

Single Subject Protocol Deviation (SSPD) Procedures:

1) A SSPD 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 convened board 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

Changes that do not 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 informed consent form
    - 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 SSPD 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