Expedited Review (HRPP 2.3)

Description:

This policy describes UNMC's requirements for using expedited review for considerations of:

1) new research proposals
2) continuing review of previously approved research
3) minor changes in protocol
4) minor complaints
5) non-serious compliance

Definitions:
Minimal Risk: the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those **ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.**

General Considerations:

All research activities considered for expedited review must be **no more than minimal risk.**

A designated expedited reviewer decides whether they have sufficient information for IRB approval.

Expedited Review Categories:

1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met:
    a. Clinical study of a **drug for which an IND application is not required** and does not significantly increase risks.
    b. Clinical study of a **medical device that is cleared/approved for marketing** and is being used in its approved manner; or an investigational device exemption **(IDE) application** (21 CFR Part 812) is **not required.**
2) **Collection of blood samples** by finger stick, heel stick, ear stick, or venipuncture:

a. *From healthy, non-pregnant adults who weigh at least 110 pounds*: the amount drawn does not exceed 550 ml in an 8-week period and collected no more than 2 times per week.
b. *From other adults and children:* the amount drawn does not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collected no more than 2 times per week.

3) **Prospective collection of biological specimens** by noninvasive means.
4) **Collection of data** through non-invasive procedures **routinely employed in clinical practice** *(not including x-rays or microwaves).*
5) Research involving **materials collected** (or will be collected) **solely for non-research** purposes.
6) Collection of **data from voice, video, digital, or image recordings** made for research purposes.
7) Research on **individual or group characteristics or behaviors or research employing survey, interview, or focus group.**
8) **Continuing review previously approved by IRB where the enrollment is closed,** all subjects have complete all research interventions, and the research is active only for long-term follow up.
9) **Continuing review where no subjects are enrolled** and no additional risks identified.
10) **Continuing review where the remaining research activities are data analysis**.

Expedited Review Actions:

- **APPROVAL**
  - All criteria for approval are satisfied and no changes are required
  - The study may start (when institutional requirements are satisfied)
- **CONDITIONAL:**
  - Minor changes are required
  - Final approval contingent upon IRB review and acceptance of changes and/or submission of additional documents
- **TABLED/RE-REVIEW REQUIRED:**
  - Major change required or there is significant missing information
  - Re-review is required and the PI has 60 days to respond

- **REFER TO FULL IRB REVIEW:** The expedited reviewer may send a study to the full IRB if:
    - The expedited reviewer is unable to determine that the protocol satisfies the regulatory requirements for expedited review
    - The expedited reviewer determines the regulatory criteria for approval are not met
    - The expedited reviewer determines the protocol has serious deficiencies which would merit disapproval
    - The expedited reviewer believes the research is more appropriate for review by the full IRB

Review by Other Committees:

Besides the IRB, other institutional committees might need to review the study (e.g. radiation safety, Conflict of Interest, etc.). Final approval only happens after these groups have provided their approval to the IRB.

Final Approval Letter:

Once all changes are accepted and other necessary approvals are in place, the ORA sends the final letter via email allowing the study to start. This letter should be read carefully as it includes:

- Important dates (review, approval, **expiration**)
- Confirmation that the study is minimal risk
- Which expedited category/ies the study falls under
- Specific federal protections used (e.g. children, prisoners, pregnant women, fetuses, neonates)
- Whether informed consent is waived or altered