

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**
 - Initiation of research authorized (when institutional requirements are satisfied).
 - All criteria for approval are satisfied and no changes are required.
- **CONDITIONAL APPROVAL:**
 - Final approval is contingent upon specific modifications and/or submission of additional documents.
 - Requirements for final approval are considered minor and not substantive in nature.
- **TABLED/RE-REVIEW REQUIRED:**
 - The reviewer requires additional information in order to determine whether the criteria for approval is satisfied.

- **REFER TO FULL IRB REVIEW:**

- 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.