

Ethical Review Processes I (Exempt & Expedited)

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Outline



- ❧ Objective
- ❧ Message
- ❧ Exempt and expedited review
- ❧ Characteristics of exempt and expedite review
- ❧ Reason for exemption and expedited review
- ❧ Conclusion

Objective



- ∞ To introduce learner to different types of protocol requiring exemption & expedited review

Message



∞ Not all protocols require full committee review

Exempted & Expedited Review



- ∞ Research involves no more than minimal risks
- ∞ Minor changes in previously approved research during the period for which approval is authorized

Criteria for Exempt & Expedited Review



- ∞ Personal identity cannot be identified
Anonymous interview
- ∞ Research data available in public domain
Review of documents e.g. hospital data

Characteristics of Expedited Review



∞ Protocol reviewed

∞ Approved

Characteristics of Expedited Review



- ∞ No meeting convened
- ∞ One member of the committee reviews the proposal & exercise authority of the full committee.

Reason for Expedited Review



- Minimal risks.
 - probability and magnitude of harm is no greater than that encountered in the daily lives of all (or the great majority) persons in the population (under normal circumstances) from which research participants are to be recruited (page 19).
- Note: Minimal risk is applicable in non-therapeutic research only

Conditions for Expedited Review



∞ Vulnerable populations not involved:

∞ Children

∞ pregnant women

∞ No serious methodological or ethical flaws

∞ Need to critically discuss disapproval of any protocol

Process



- ∞ Adequate information must be submitted, sufficient enough for the committee to make decision

Process



- Exempted may be given by the committee chairperson or his/her designee within the committee in consultation with the administrator

Process



- ❧ The chairperson shall bring all exempted and expedited research to the next meeting of committee for
 - ❧ Notice
 - ❧ Discussion and
 - ❧ Ratification

Conclusion



- ❧ Regardless of the nature of review research will undergo ethics committee members should pay attention to:
 - ❧ Risk
 - ❧ Benefits
 - ❧ Social Value
 - ❧ Qualification of Researcher(s)